

ZAN500 Body plus CO-Diffusion

Operations Manual

Part Number : 5001005ENG

Version / Revision : A

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Thank you for purchasing the Flow Handy ZAN500 Body System.

The product complies to the newest state of technical development. In order to improve the lifetime of this product, only materials of extremely high quality are used. All materials are environmentally safe and can be recycled.

The manual provides instructions for operating the ZAN 530 Body system.

The instructions in this manual assume the user is familiar with the intended use and application of pulmonary-laboratory systems.

To avoid damage to the devices or incorrect measurement, it is strongly recommended to follow the introductions in the manual and the technical description.

This manual is seen as part of the product, according to DIN EN 60601-1 :1996. It should be kept near to the device. Additional safety hints, according to German Medical Products Law, can be found in chapter A8 "Safety, Maintenance, Service".

Your nSpire Health-Team



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Documentation Conventions

The following format conventions are used in this document to identify special information:

Warning: statements identify conditions or practices that could result in personal injury.

Caution: statements identify conditions or practices that could result in damage to equipment or loss of data.

Note: The graphical illustrations in this document are for example purposes only and the hardware illustrated may differ from your hardware.

Safety Precautions

The ZAN hardware has been tested and certified to be compliant to UL 2601-1 and CAN/CSA C22.2 NO. 601.1. Type I equipment electric shock protection is provided by 3-wire power cord earth ground and additional external earth ground as described. However, the following precautions must be observed for auxiliary equipment:

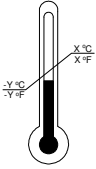
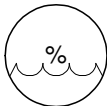
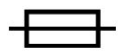
- a. Connect the power cord for each individual component to a wall source.
- b. Do not connect extension cords to the system.
- c. Do not use multiple power strips; and only use the power strip that is supplied by nSpire Health.
- d. Operate the hardware device only when the power cords are plugged into "U" grounded outlets (3-hole outlets).
- e. Unplug the power cords prior to servicing the equipment.
- f. Computer, monitor, printer, and testing unit are components fit for use within the patient environment, provided external grounding has been implemented as per instructions.
- g. The User/Operator must not touch any non-medical device (that is, any device other than the testing unit) and the test subject at the same time.
- h. The ZAN hardware (ZAN100 USB) has been tested and meets the latest EMC requirements for immunity and emissions of IEC 60601-1-2. However, electromagnetic interference may still be encountered. If the device is behaving erratically due to electromagnetic interference, contact nSpire Health customer support.

- i. Do not connect items that are not specified as part of the ZAN hardware (ZAN 100)
- j. Do not operate the ZAN hardware (ZAN100 USB) or other system components on any voltage other than that specified.
- k. All flammable materials must be kept away from the equipment and “No Smoking” signs must be prominently displayed in the testing area.
- l. Oil and grease must be kept away from oxygen equipment.
- m. Oxygen-approved regulators must be used for O₂ tanks.
- n. The equipment is a Type IIA device that requires the use of a 3-wire Type I cord-set.

 **Warning: For Denmark, it is extremely important not to use the Schuko CEE 7/7 plug; it will mate with the Danish socket, but it will not be grounded. This may result in serious safety hazards.**

- o. According to good hygiene practices, filters and/or mouthpieces that came into direct contact with the subject's mouth or aerosolised droplets from the subject's effort should not be touched. Dispose of filters and mouthpieces as ordinary waste, or as specified by your institution.

Labelling Glossary

Glossary of Common ISO Symbols ¹	
	High Voltage
	Item for single use (do not use more than once).
	This symbol indicates that the user must read and understand all instructions and warnings prior to use.
	Acceptable Ambient Temperature Range: Indicates the upper and lower temperatures allowed for transport and storage.
	Protective earth ground
	Indicates the date by which the product must be used, in the format Year.Month.Date (e.g., 2005.02.19)
	Type B Equipment: Equipment providing a particular degree of protection against electric shock, particularly regarding: allowable leakage current and reliability of the protective earth connection (if present).
	Heavy weight.
	Alternating current
	Fragile.
	Direct current
	Keep Dry.
	Power on
	Transport and storage humidity conditions.
	This symbol indicates that this Class IIA equipment complies with the guidelines concerning medical devices 93/42/EEC of the council from 14.Jun 1993.
	Power off.
	Fuse
	This symbol indicates that the associated jack is for a USB (Universal Serial Bus) connection.

¹ International Standard, CEI IEC 417P, Graphical symbols for use on equipment, first edition, 1973

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1 System Description

1.1 Overview

1.1.1 General Information

The medical product ZAN 500 Body is a PC based constant volume body plethysmograph. It consists of the hardware components (chamber and control unit) and specifically designed software. All common lung function tests can be performed with this equipment.

The software, delivered with the device, is designed to run on standard PCs. It operates on MS Windows® operating systems like Win98SE, Win2000, WinXP and VISTA. It does not operate on WinNT due to missing USB support.

ZAN 500 Body is built mainly for functional diagnostics of the lung in a clinical environment as well as in practices of specialised physicians.

1.1.2 Special Features

- **USB Interface**

The connection to the PC is through a USB interface. This type of connection is less complicated and faster than traditional serial interfaces.

- **NDC Numeric Drift Compensation**

A particularly special feature of the ZAN 500 Body is the numeric drift compensation. This newly patented feature guarantees stable resistance curves right from the start of the measurement.

- **CO Diffusion**

In addition to the features of the ZAN 500 Body, the ZAN 530 Body includes the CO Diffusion test hardware and software components.

- **PC Software**

A simple user interface grants optimised learning, with safe and easy use.

- **Integrated Medication Presets Database**

Medication presets can be added and edited at any time. There are tables of standard values predefined in the software which can be edited or added to. Additionally it is possible to add predicted normal equations, which can also be edited any time.

- **Integrated Patient Archive**

Archived data and measurement results can be retrieved and printed at any time using the printing facilities of Internet Explorer ®. All data and results can also be computed and examined manually either directly after the measurement or, if the data has been archived, at a later stage.

- **Data Import/Export Interface**

External data exchange using HL7 is available.

- **Manual Re-measurement**

Almost every curve can be re-measured manually using tangential adaptation. This can be done right after the data acquisition or later after the data has been archived and retrieved.

1.1.3 Safety Advice

Warning: The Flow Handy ZAN 100 USB device must only be used in connection with PCs and peripheral devices which are compliant to DIN EN 60950 and also have a valid CE clearance.



Plugs and connectors must not be connected to any device other than those mentioned in this manual

The opened door of the cabin must not be pushed downwards as this may cause the unit to tilt.

Patients should be shown the internal door release switch prior to closing the door.

1.2 Hardware

1.2.1 System Overview

The system consists of two main components: the chamber and the control unit, which itself consists of the system desk, the PC unit and the power supply.



Test gas cylinder is not displayed on this picture.

1.2.2 Body Box

The test chamber, also called the body box, is the main component of the body plethysmograph. It is completely transparent, minimising feelings of claustrophobia. Patients usually feel more relaxed and cooperate better.



In order to enable easy communication between the patient and the operator, an intercom is situated in the right sidebar of the door.

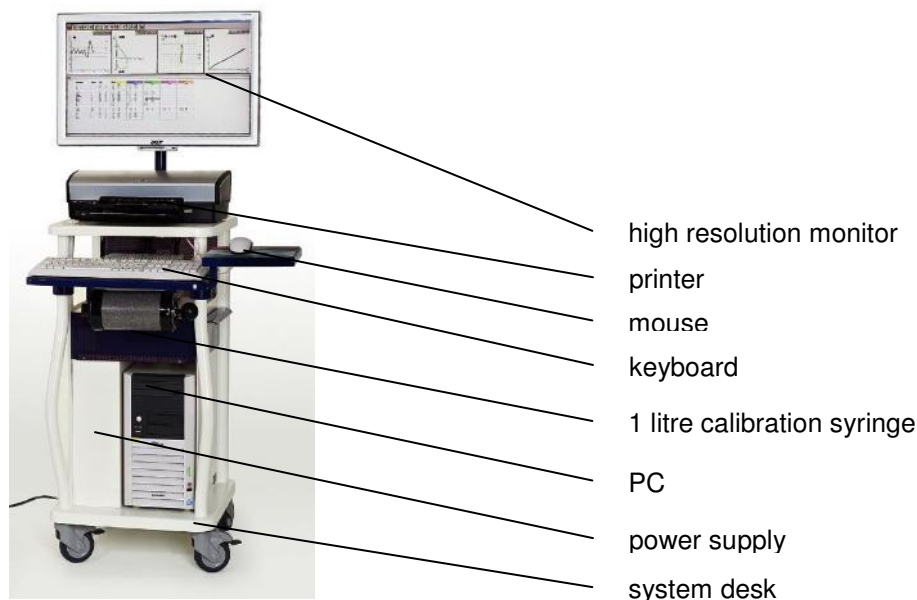
The stand height can be adjusted using the external controls, allowing the operator to adjust the height without opening the chamber door or disturbing testing.

The door is locked by electronically controlled magnetic locks, which can be unlocked from the outside as well as from the inside.

Important: Every patient should be aware of the red door-release button. Showing your patient how to unlock the door may help to avoid unnecessary anxiety.

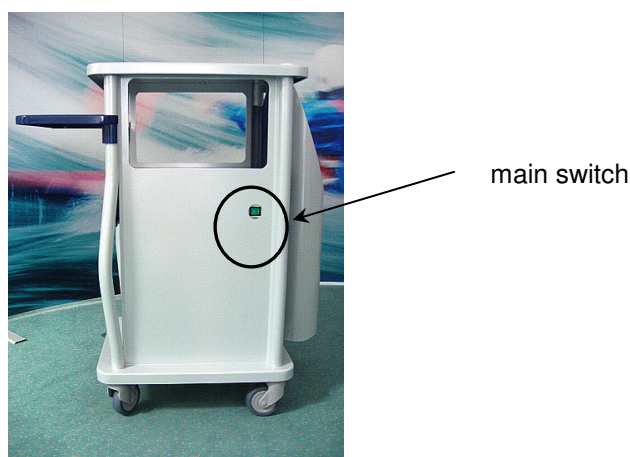
1.2.3 Control Unit

All necessary external devices to operate the body plethysmograph are integrated in the control unit. All devices receive their operating current from the integrated power supply. This specialised power supply ensures that all connected devices are electrically isolated.



nSpire Health provide special wide screen monitors with the system to support optimal viewing of the whole user interface. These high resolution monitors are connected to the system desk with an adjustable arm. As an incentive or to allow the patient to read the onscreen instructions, the monitor may easily be repositioned so that the patient may view the monitor from inside the body box

The main power switch for all components, including the chamber, is on the system desk.



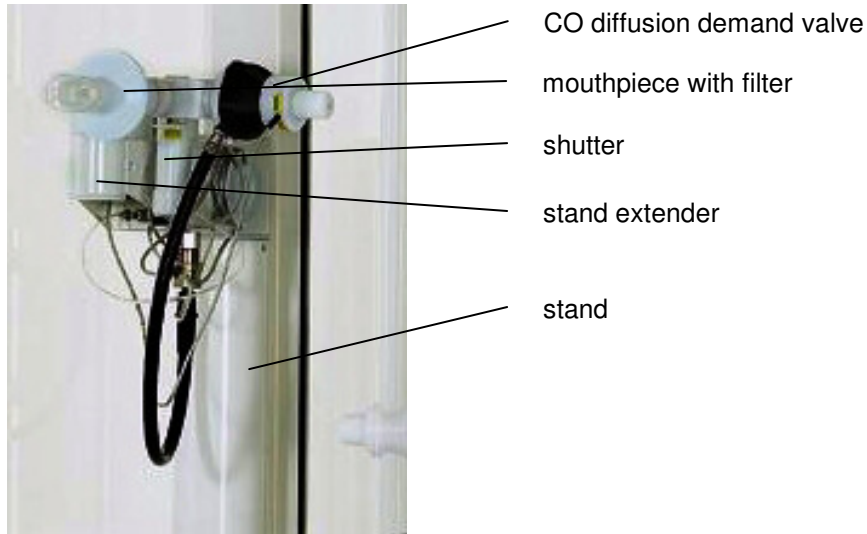
Caution:



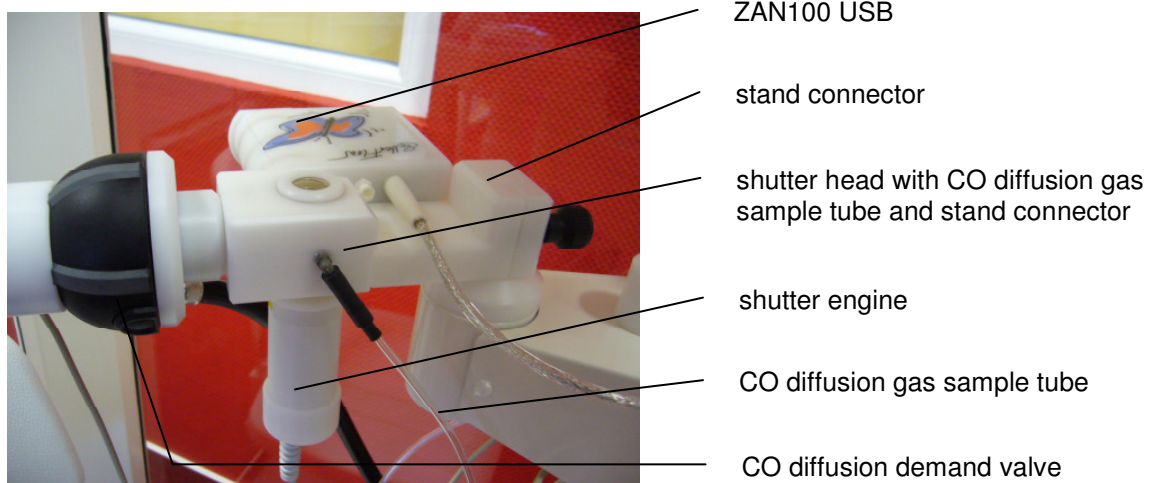
Do not switch off the main switch while the PC is still running. This could cause loss of data and damage the operating system. Always shut down the PC before turning off the main power.

1.2.4 Measurement Unit

The measurement unit is connected to the externally controlled stand.

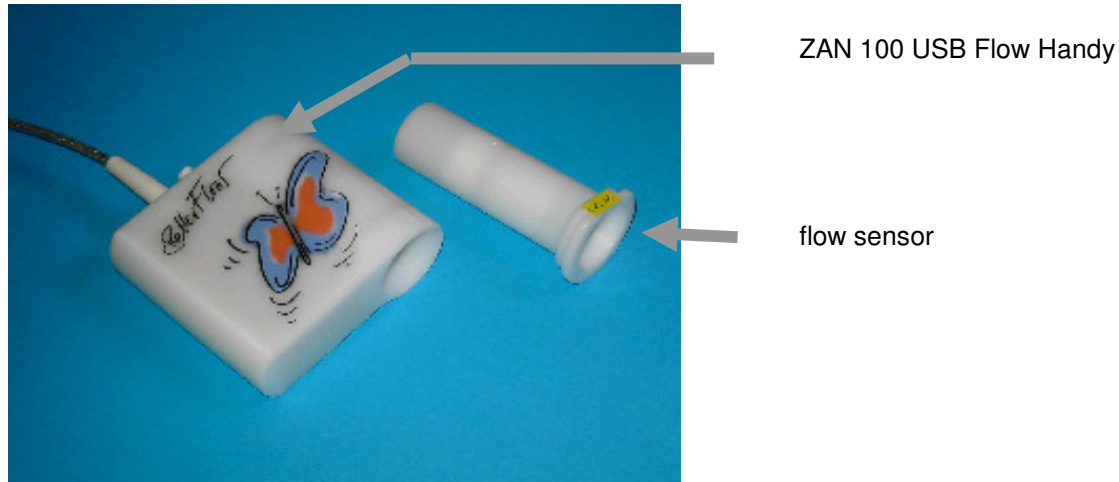


From a different angle the other components can be seen. Please note the mouthpiece and the filter have been removed for this picture.



All parts have plug-in joints and the measurement unit can be disassembled without tools.

Flow Handy ZAN 100 USB



1.2.4.1 Flow Sensor

Like traditional pneumotachs the flow sensor works by measuring the pressure drop across a flow resistance.

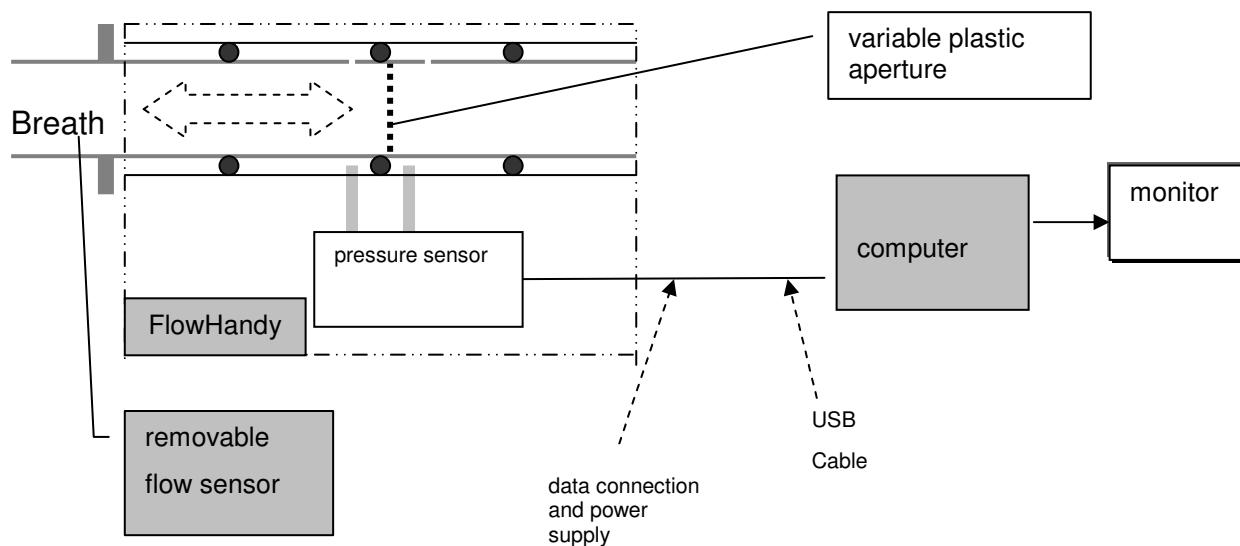
With the ZAN flow sensor the resistance to flow is created by a variable plastic aperture. Due to its low resistance, the aperture will not create additional breathing load.

The sensor works quietly and is insensitive to moisture from exhaled air.

As a result even patients with severe breathing difficulties can be examined

- without significant CO₂ backbreath
- without significant resistance.

1.2.4.2 Diagram of the Flowhandy ZAN100 USB



1.2.4.3 Shutter

1.2.4.3.1 Operational principle

An electromagnet moves a closing piston inside a sealed tube sealing the upper and the lower rims at the same time.

Using this approach, the shutter is virtually free from backflow.

The shutter unit, attached to the end of the ZAN 100 USB, is connected to the PC via the body box or an AccuSwitch USB device.



1.2.4.3.2 Special properties

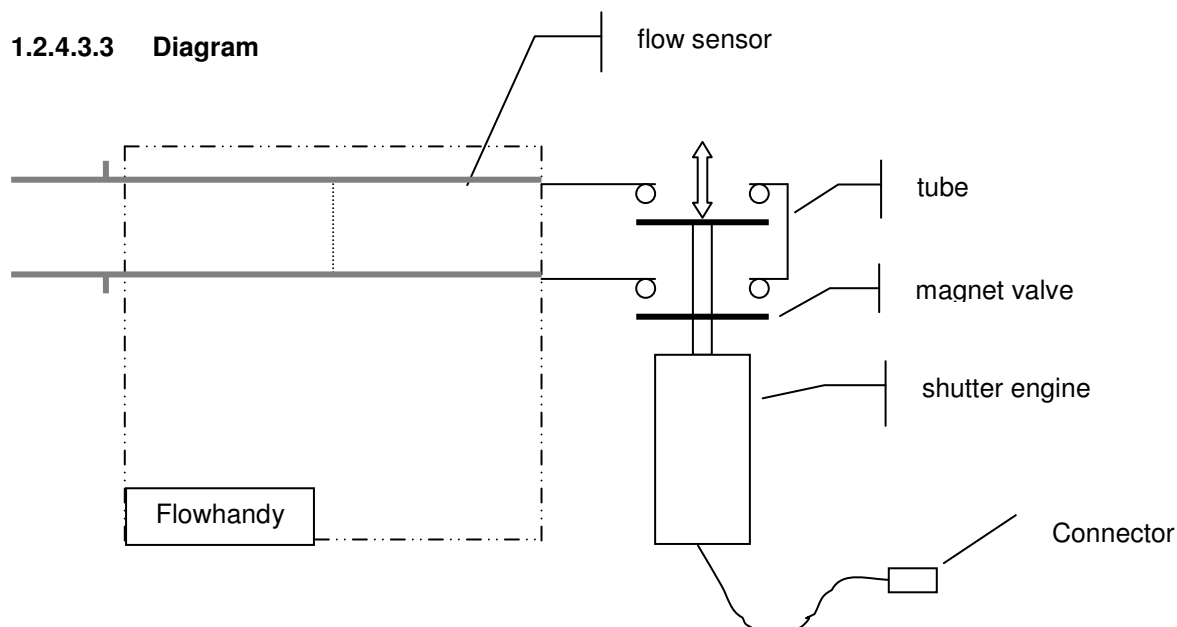
Due to the low flow resistance of the shutter, a flow/volume loop can be carried out with the valve attached.

The shutter also has a very small dead space and does not influence the quality of the flow measurement.

The device can be disassembled without tools.

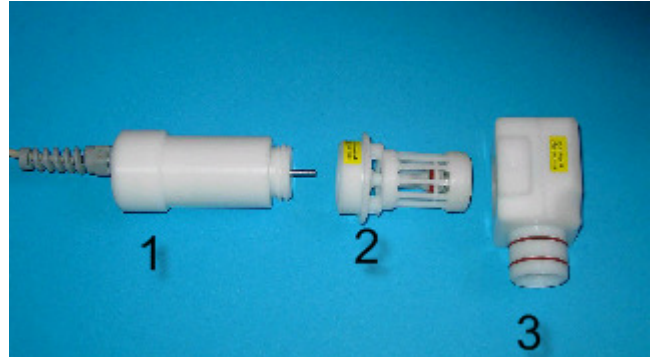
The interruption is carried out perpendicular to the respiratory flow. Consequently, the interruption is perceived as very comfortable by the patient.

1.2.4.3.3 Diagram

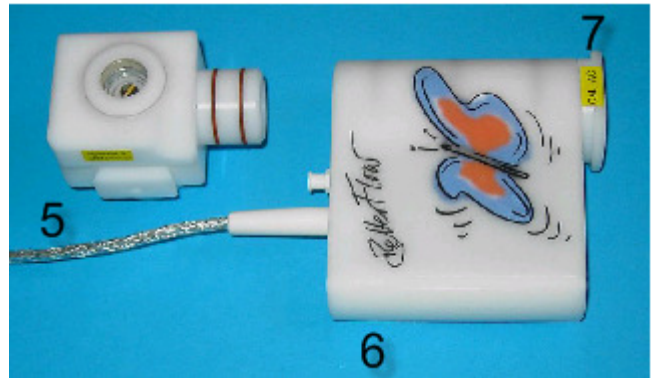


1.2.4.3.4 Assembly and Attachment of the Shutter

1. Shutter engine
2. Magnet valve
3. Shutter head

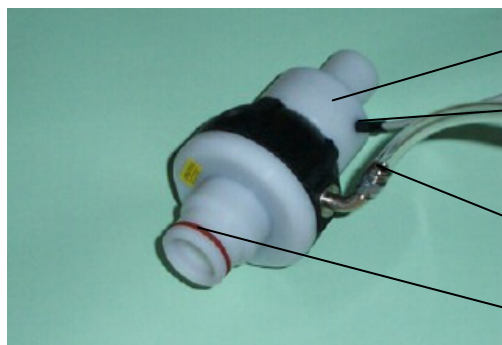


- 1 Push the shutter (5) into the rear of the Flow Handy ZAN100 USB (6).
- 2 Make sure, that the flow sensor (7) is completely inserted in the Flow Handy ZAN100 USB (6).



1.2.4.4 CO Diffusion Demand Valve

The CO diffusion demand valve is an additional component, required for the CO diffusion test.



magnet valve

electronic control cable

test gas tube

plug in connector to the shutter head with o-ring

The valve is plugged directly into the shutter head. Please properly maintain the o-rings. They should be covered by a thin layer of Vaseline (accessories) to make them slide easily into the shutter head.

Caution: Replace damaged o-rings before testing!

1.2.4.5 Cable Connections

Cable and tube connectors can be found on the underside of the stand arm.

moveable stand arm

connection for the shutter

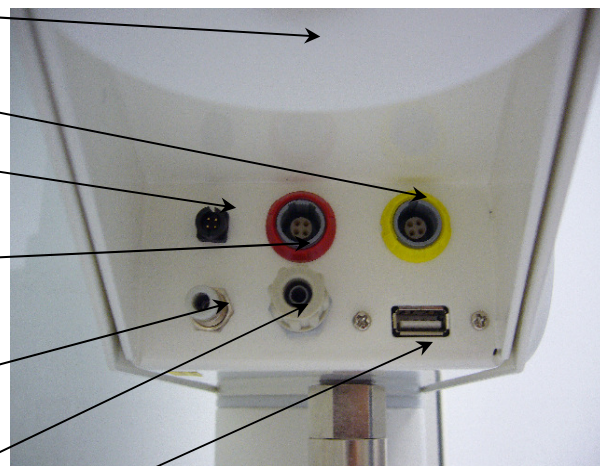
plug-in connection for the power supply of
the demand valve electromagnet

control connection for the ZAN200 Provair
dosimeter

connection for the CO diffusion sample
tube

Compressed air outlet for the
nebuliser (ZAN200)

USB connection for ZAN100
Flow Handy



1.2.4.6 Body Box Controls

1.2.4.6.1 Outside

On the outside right door panel can be found the chamber controls.

door release
button

door closed LED

microphone

Stand height adjust
(up)

Stand height adjust (down)

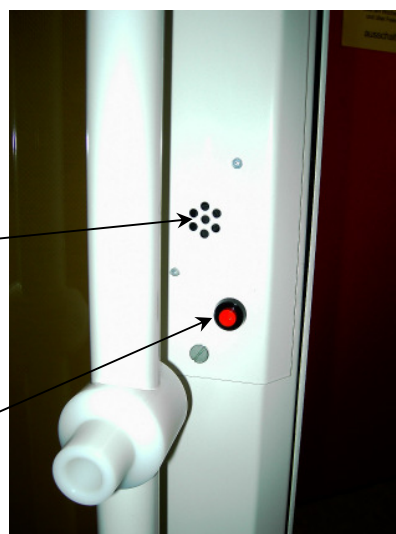


1.2.4.6.2 Inside

Inside the chamber on the same right door panel are the door release button, speaker and temperature sensor.

microphone
and speaker

door release
button



1.2.4.6.3 External connectors of the chamber

Underneath the body box are the external connections.

From the left to the right:

1. compressed air from ZAN200 ProvAir
2. CO Diffusion sample tube (to analysers)
3. CO Diffusion test gas input
4. USB-connector to the PC
5. ProvAir remote control cable
6. Power supply input (12V)
7. Power supply input (24V)



1.3 Software

The ZAN GPI 3.00 software provides a patient data management system, measurement programs and a database for measurement results.

Archived data and measurement results can be retrieved, viewed and printed at any time.

Refer to Chapter 2 for additional information. A detailed description of the installation can be found in Chapter A2. A guide to customisation of the system according to your personal needs is in Chapter A5.

1.3.1 PC System Requirements

Minimum Requirements

Operating system	WIN 2000, WIN XP
CPU	Pentium IV, 1.89 GHz or better
RAM Size	500MB
Hard disc	40GB
Installation drive	CD-ROM
Device interface	USB 2.0
Monitor:	20" Colour monitor
Screen resolution	1280x1024 Pixel or better
Printer	colour

1.3.2 Content

Standard procedures are:

- SVC
- Flow/Volume
- Combined SVC/FV
- Body plethysmography

CO diffusion is part of the ZAN 530 Bodyplethysmograph.

Optional available procedures are:

- Provocation Test
- Rocc
- MVV
- P 0.1
- Rhinomanometry
- Compliance
- Sniff

1.3.3 NDC Numeric Drift Compensation

Patient's body heat will cause the temperature inside the box to continuously rise until it eventually reaches equilibrium. Opening the door of the box will momentarily reduce the temperature. These temperature drifts can cause erroneous results so on older body plethysmographs it was essential to wait for temperature to equilibrate.

nSpire Health has developed an advanced digital signal processing which instantly compensates for drift. It is no longer necessary to wait until the temperature within the chamber has reached equilibrium – the measurement can be performed almost immediately after the door is closed. This means the measurement, even under extreme environmental conditions, is virtually free from artefacts.

NDC drift compensation is designed to remove warm up time and compensates for about 95% of drift and environmental interference.

1.4 Operational Principle

1.4.1 General Information

The cabin is designed to be airtight when the door is closed. The pressure inside the cabin is then measured against a compensation chamber, which is located underneath the cabin, using a differential pressure transducer. This approach minimizes the effect of ambient pressure fluctuations on the actual cabin pressure signal.

The patient breathes through the ZAN 100USB mouthpiece, allowing his/her flow and volume to be measured.

A pressure transducer located inside the 100USB measures the pressure at the mouth.

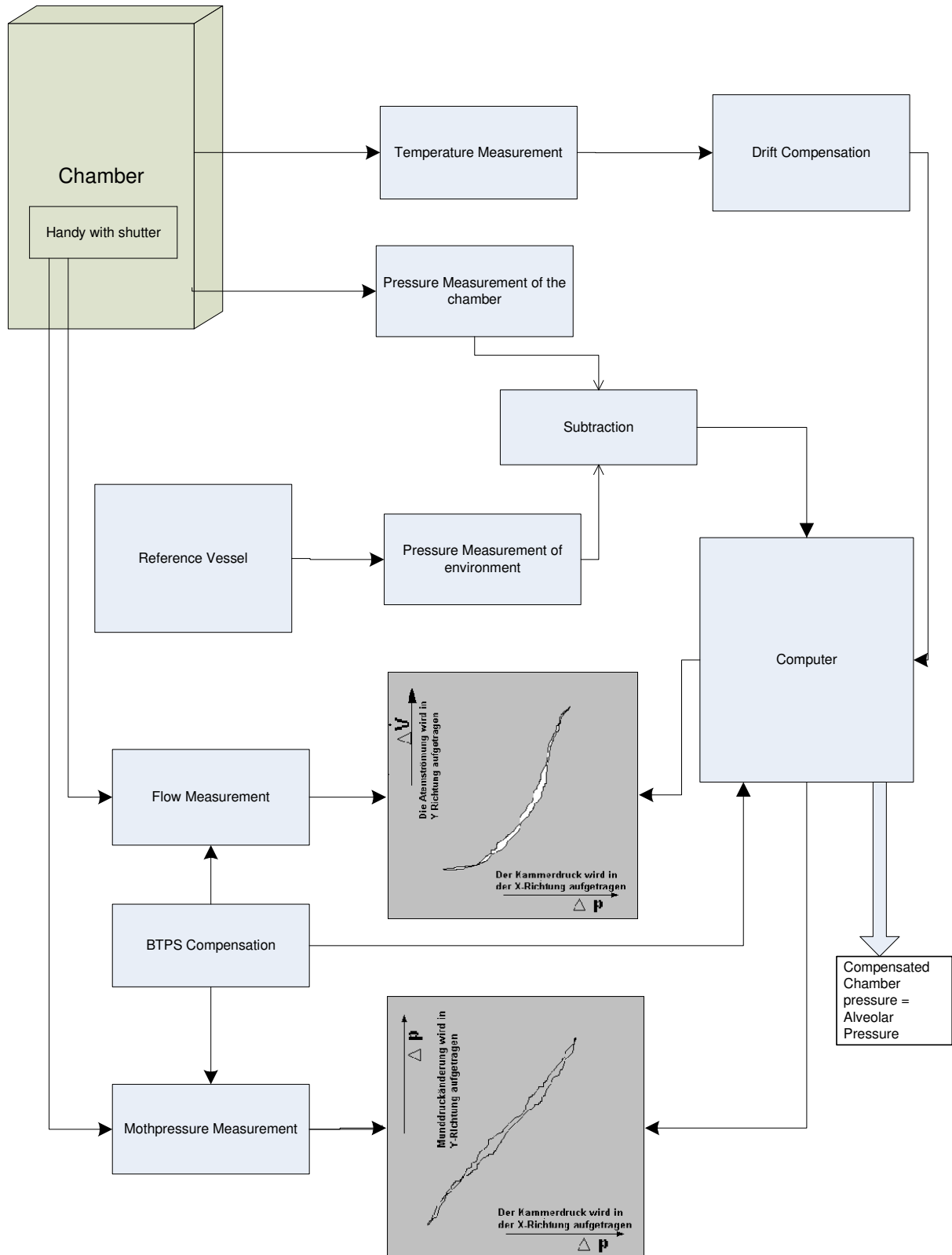
The digitised data from all pressure transducers are then transmitted to the PC and corrected for BTPS when appropriate.

1.4.2 Measured Parameters

From the measured data, the following parameters can be computed.

RAWtot	RAWex	RAWin	Gtot	Gex	Gin	sRAWtot	sRAWex
sRAWin	sGAWtot	sGAWex	sGAWin	ITGV	ITGV	RV	TLC
ITGV/TLC	RV/TLC						

1.4.3 Operational Diagram of the Bodyplethysmograph



1.5 Test Procedures

The ZAN 500/530 body plethysmograph can perform various tests. Each test is explained in detail in Chapter 4.

1.6 Special Information

Important! In order to receive precise results, the user must be familiar with the handling of the device and the software. It is strongly recommended the user reads the user manual prior to examining any patients.

The user should also be familiar with security and measurement technical issues. Please read the security information in the corresponding chapter.

1.6.1 First Startup

Before the device is turned on for the first time, the software must be installed on the PC.

You will find the description of the installation procedure in the addendum as well as a system checkup description.

Refer to the FAQ section for additional troubleshooting help.

1.6.1.1 Voltage Supply

Always use the delivered ZAN power supply for energising the system.

If you use a ZAN system cart, the power supply is connected to its socket strip. If ZAN 530 is not part of a system cart, it must be connected directly to a wall socket.

The green LED on the side of the ZAN 260 trolley indicates whether the device is switched on or off. Use the power switch on the side of the ZAN 260 to power the unit on and off.

1.6.1.2 PC Connection

The ZAN 530 is directly connected to the PC's USB interface over a USB extension. Please do not use a hub between ZAN 530 and the PC.

Immediately after connecting the USB plug with the PC, the PC will recognise the USB device and automatically select the appropriate driver.

1.6.1.3 Connecting the CO Diffusion Gas Cylinder

To calibrate the multi gas analyser, a cylinder of calibration test gas must be connected to the ZAN 530 with an approved and tightly fitted pressure regulator, set to 50psi. Please adhere to the usual precautions when dealing with gas at high pressure.

The large bore tubing is used to connect the regulator to the blue push-fit gas input (3) connector on the underside of the body box (external connections). The smaller bore tubing connects the grey push fit connection (2) to the 'Cal Gas' port on the rear of the multi gas analyser.

For safety reasons the calibration gas cylinder must be secured to prevent it from falling.

On the ZAN system cart, there is a special holder for the gas cylinder.

If a system cart is not available, the gas cylinder must be fastened to a wall.

The diffusion gas is comprised of a mixture of 0.3% Carbon monoxide (CO), 0.3% Methane (CH₄), 21% Oxygen (O₂) with balance Nitrogen (N₂).

1.6.2 Daily Tasks Before Testing

Check that all cables and tubing is well connected.

Check the o-rings, essential to a leak-tight system, are in place and are in good condition. The o-rings on a ZAN system are made of silicone and must only be replaced by ZAN o-rings.

Calibration should be verified.

1.6.3 Before the Measurement Starts

For hygiene reasons only properly disinfected filters and mouthpieces must be used.

Before the measurement starts, make sure that the flow sensor is properly inserted inside the flow handy body. It has to be inserted completely and the flat portion of the front rim should point upwards.

Careful instruction and explanation to the patient is essential.

During zero adjustment the patient must NOT breathe through the device.

The mouthpiece must be connected firmly to the flow sensor. The patient should use a nose clip and form a tight seal around the mouthpiece with his or her lips.

1.6.4 Hygiene

Users should always adopt appropriate hygiene practice when dealing with contaminable parts.

All contaminable parts should be dismantled and disinfected.

Refer to Chapter 9 (Disinfection) for appropriate procedures and cleaning agents.

Only disinfected flow sensors, mouthpieces or face masks may be used.

Caution Always consider the recommendations from the disinfectant manufacturers concerning concentration, purpose, and reaction time. The responsible physician has to control the proper use and appropriate intervals.

2 User interface

The ZAN GPI 3.xx software interface is designed for ease of use. The list of patients and the measurement results are shown in the form of an 'index' card (tabular form) on the screen.

There are 4 programme modes:

Patient	Mode
Measure	Mode
View	Mode
Archive	Mode

The visible 'index card' lets you handle the data sets of up to 5 different patients simultaneously. You can switch to single patient mode using the set-up [alt/S].

The number of patients in the archive is only limited by the capacity of your hard drive.

Software navigation is simplified by using the buttons on the right hand side of the screen allowing quick access to entering patient biographical data, for performing tests with the measure button, to view results of tests performed today (or in the past) and to archive the results to the database.

Note: 'To click on' or 'select' means to move the cursor over the desired button and then press shortly the **left** mouse button.

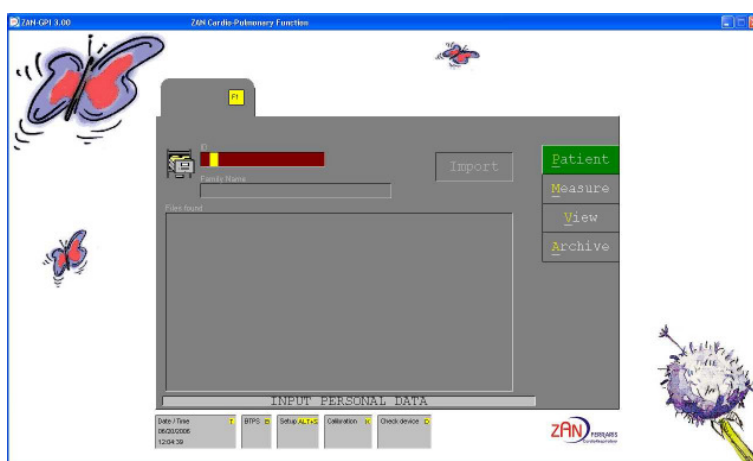
You can also select an option with the keyboard. Use the yellow coloured characters to activate the desired option.

2.1 Activating the Programme



After successful installation, clicking on the ZAN icon on your desktop activates the programme.

You see the index card →



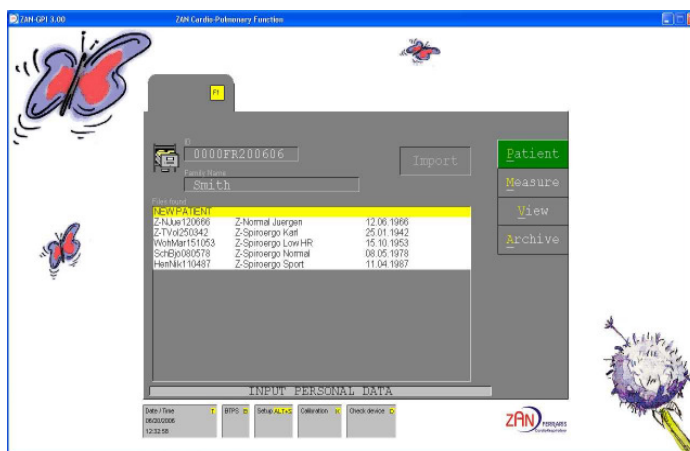
2.2 Patient Data Entry

Select a blank tab form either with the mouse or the keyboard and enter the surname (just the surname without any add ons). Press the **[enter]** key.

The system will now check the database to see if this name has been stored before.

If so, you will see a list of all patients with this name. Additionally this list contains an entry "NEW PATIENT".

Using the mouse or the arrow keys, you can select a patient or the "NEW PATIENT" Option to enter a new one. Press the **[Enter]** key to confirm the selection.



If you select "NEW PATIENT", an input form appears.

Each field should be completed with the relevant data and confirmed with **[Enter]**. The cursor will automatically jump to the next field.

Accurate patient biographical data is crucial for the calculation of reference values.

It is important to ensure the correct format is used for each field. If the wrong format is used in the date of birth field (correct format: MM/DD/YYYY), it must be corrected to continue

Note: If all Tab forms are in use, use the 'Archive' option to free one.

2.2.1 Input Formats

Field	Format	Remark
Family Name	All letters	The first 3 letters are used for an automatic ID number.
First name	All letters	The first 3 letters are used for an automatic ID number.
Date of birth	MM/DD/YYYY	Month/Day/Year. Leading 0 does not have to be entered, but the slashes between the dates are required. The input of century or millennium can be left out, if the patient's age is below 100.
Height	in.	Input is limited between 20 and 100.
Weight	lbs.	Input is limited between 2.2 and 551.
Sex	Selection with arrow keys	← → or with the mouse
Comment	All letters	Free form text.

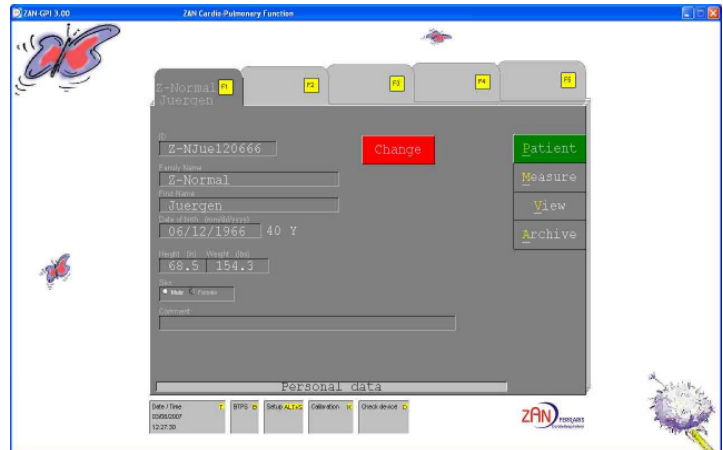
Caution: If the cursor does not leave the input field, it is likely the input format is wrong. This happens frequently in the date of birth field, but check all data fields for format errors anyway.

Save

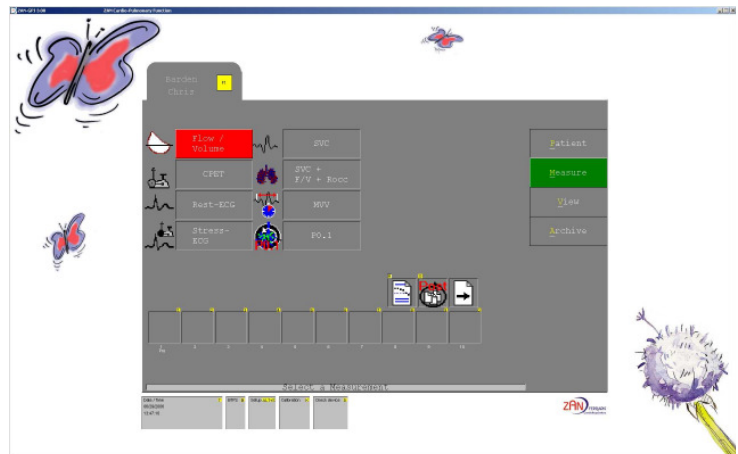
Once all fields are completed, the record can be saved using the save button.

Caution: If the cursor jumps into the **ID-No.** field, this indicates that the automatically determined ID-No. has already been assigned to another patient. As patient data must be differentiated, the ID-No. must be modified manually.

Press the save button again.



The patient's name will appear at the top of the index card. The system is now ready to begin testing.



2.3 Modifying Patient Data

From the measurements screen, click the Patient button to open the patient data field for the current patient.



Once the patient file is open, the Change button will become available. Click this → to enable changes to the patient data file.



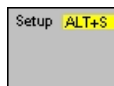
After the desired changes have been made to the data, select the Save button.



Note: Archived data can also be modified in this way.

2.4 Entering Additional Patient Data (Optional)

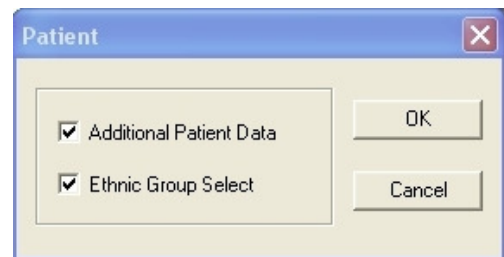
This option can be selected to add additional patient data for each patient.



Access the Set-up menu using this icon (located at the bottom of the screen). From this menu, select Patient.

Note: This is password protected and should be set up by your representative during installation. Please contact your representative for further information.

On the Patient dialogue box, click the Additional Patient Data checkbox.



Once the required selections have been made, the ZAN software must be **restarted** for the desired changes to take effect.

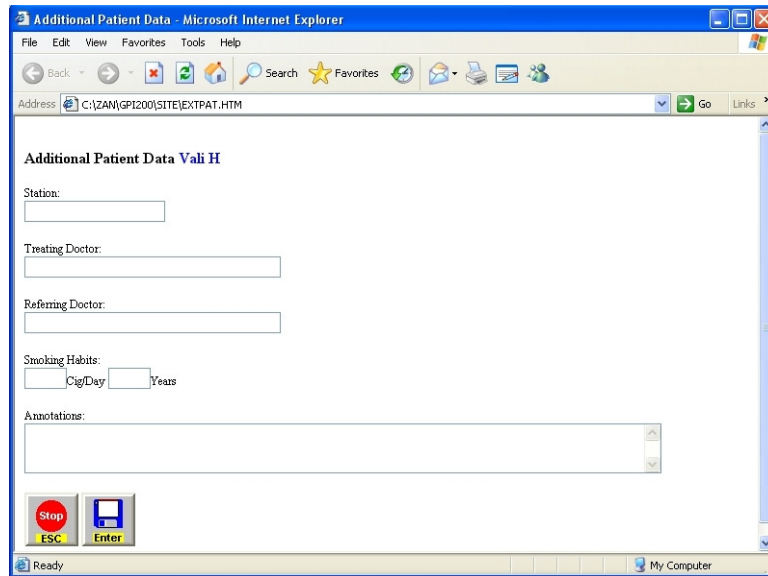


Once the additional patient data has been activated, it will be available within the patient data screen.

By clicking on the Extended button, the Extended Patient data screen is then opened



and can be completed in the same way as the Standard Patient data screen.



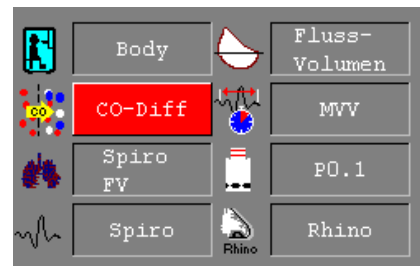
When the required fields have been completed, select the [Enter] key to save this data.

2.5 Measurement Mode

Once the input of Patient data is complete, measurements can be performed on the active patient. Select the Measure button from the menu or press [M] to display the measurement mode screen.



Select the required test.



Note: The options available on this menu will vary according to the installed components and hardware.

2.5.1 Symbol Definitions

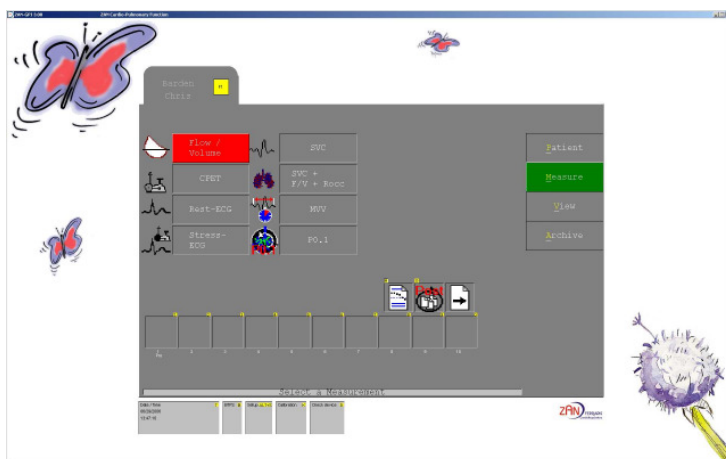
before a Measurement	during a Measurement
 Cancel the measurement	 delete previous recordings and go on with the measurement
 Shutter test	 delete FV loop on screen
 Zero the flow sensor (Patient must not breathe into the flow sensor !)	 Shutter test
 zoom in	 Zero the flow sensor (Patient must not breathe into the flow sensor !)
 zoom out	 Activate Shutter for Rocc test
 choose medication	 save and terminate
 identify current user	
 Notes	
 display the incentive graphs. With each click, the incentive graph changes to a new selection.	
 Start measurement	

Select the measurement programme using the mouse or the arrow keys $\leftarrow \rightarrow$

The programme is selected, when the corresponding field is displayed in red.

The measurement programme starts either when you click on the selected field again or by pressing the [Enter] key.

Refer to the corresponding chapters for explanation of the particular measurement programme.



Once the measurement is completed, all tests can be reviewed, compared, and printed under the View mode by clicking the View button or pressing the [V] key.

View

2.5.2 Symbol Definitions



automatically select best curve



print report on screen



change pre-, post assignment



show tests from the first on



print report



change position



provocation test (optional)



enter remarks



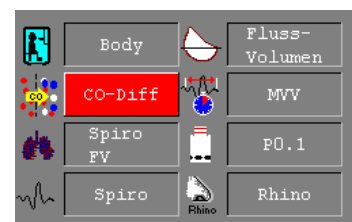
delete measurement



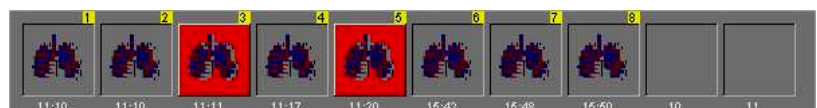
show more tests (>10)

2.5.3 Review measurements of the day

After selecting the measurement type, all measurements of this type, taken on this day are displayed.



Click on the appropriate field to select one or more from the list and display them on the screen.

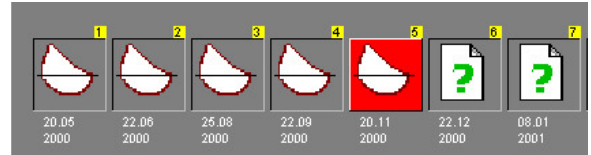


2.5.4 Displaying Archived Measurements

To view measurements performed previously (week, month, or year) on the same patient, access the archive folder with the Archive button or by pressing the [-] key.



Archived measurements are displayed in fields 1-10, labelled with the date on which they were performed.



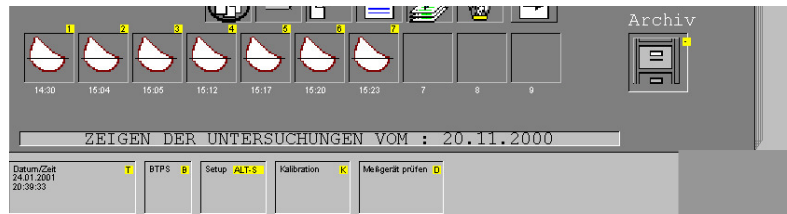
The question mark (?) indicates that on this day the patient folder has been opened, but the measurement has not been performed.



Select a date with the mouse and 'close' the archive by pressing the [+] key.



A list of all measurements on this day, labelled with their time, shows up.



Select the measurement, you would like to see.



Then click on  to select the desired report type and press **[ENTER]** to print the report.

2.5.5 Comparing Measurements of Several Days

From the Archive menu it is also possible to compare measurements that were made on different days. This is achieved by double clicking on the Days to Compare Button

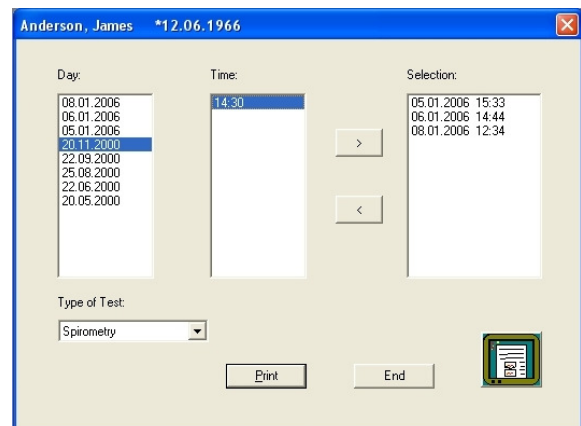


This opens an options box.

This options box enables the user to select tests from a specific day and time to be included in the comparison. Tests can be moved into the Selection Window using [>] (or removed with [<]).

The type of test for comparison may be modified by using the drop down menu in the bottom left corner. When the desired tests have been selected, the print

key  will print these results to the local printer.

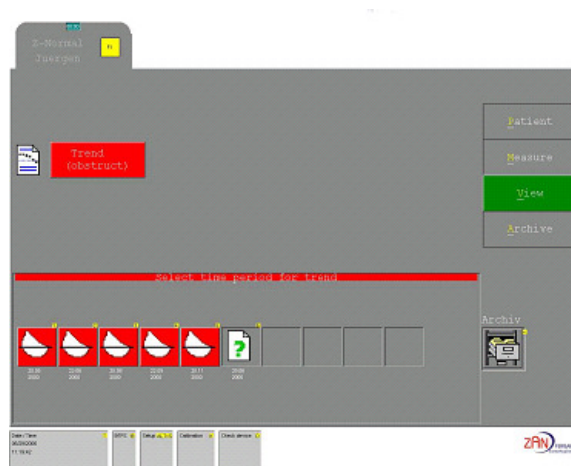


The print preview option opens the report in Microsoft Internet Explorer® for viewing on screen and this will also enable changes to the printer set-up.

2.5.6 Trend Graphs

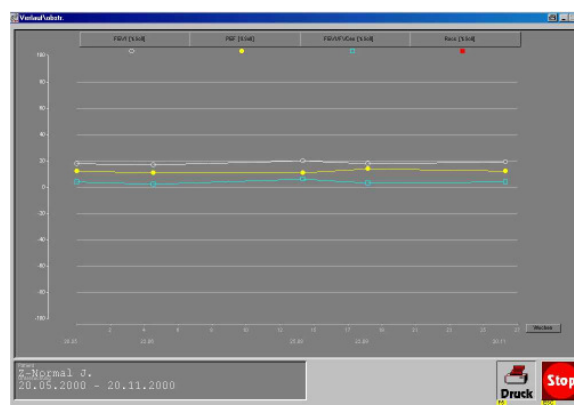
From the Archive menu it is possible to create a Trend graph for either restrictive analysis or obstructive analysis using one of the Trend buttons.

After clicking on the Trend button, a window is displayed that enables the selection of multiple tests for trending analysis. Once the desired tests have been selected, it is possible to view the trend graph by clicking the Trend button or pressing [Enter]. See Trend graph screen on next page.



Trend (restrict) creates a trend of Static Lung Volume values VC, TLC, RV, and RV/TLC.

Trend (obstruct) creates a trend of spirometry values FEV₁, PEF, FEV₁/FVC, and ROCC.



2.6 Archive or Delete Files

From this menu the user is able to perform the following functions on the entire patient file:

Archive

Archive: Automatically archives the entire patient file to the database.

Paper basket: Completely deletes the current patient file.



Caution: If confirmed, this action is not reversible



Export: Exports the complete ZAN patient files to a specified location for import.

2.6.1 Archive

Use the [Archive] option to write your Patient Data to disc.

2.6.2 Waiting Room (optional)

Pressure tube waiting room option, data is stored in an intermediate storage place. As long as there is joining olive intermediate storage, a waiting room symbol will remind you that it is being stored there. adapter and intermediate storage, select an empty index card, select the waiting room icon and recall ZAN 100 one of the listed patients.

Once all patients are removed from the waiting room, the waiting room icon disappears.

2.6.3 Paper Basket, Delete Data

If a Patient folder has to be purged, select the paper basket.

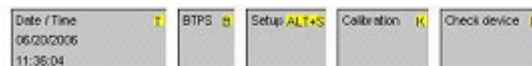
The paper basket option completely deletes the current patient file.



Caution: If confirmed, this action is not reversible.

2.7 Additional Functions

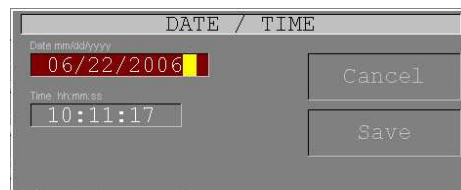
This menu is located below the index card and can be used to alter some of the system settings and other important functions.



2.7.1 Change Date and Time

Pressing the [T] key or clicking on the Date / Time box with the mouse, enables the user to change the date and time if necessary.

Ensure that seconds are entered when changing time values!

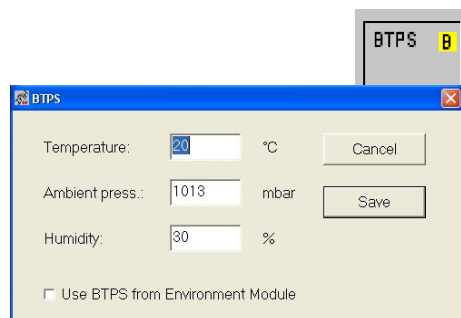


Caution: Ensure the date is adjusted correctly. This could affect a patient's age and the appropriate reference values

2.7.2 Entry of Ambient Conditions

Pressing the [B] key or clicking on the BTPS box with the mouse enables the user to change the values for ambient condition.

(Only in the Bodyplethysmograph or when using the environmental unit, these data are automatically detected and transferred)



Caution: Correct temperature adjustment is very important. A mistake of 2 degrees will cause a drift in breathing of about 1 percent.

The absolute barometric pressure must also be entered into the system. Meteorological barometers indicate a pressure, which can be converted according to the sea level.

Note: For each 100 meters of altitude, the pressure will lower by 12 mbar.

For Example: The meteorological barometer indicates 1000 mbar at 680 meters above sea level.
 $1000\text{mbar} - (6 \times 12\text{mbar}) = 1000 - 72 = 928 \text{ mbar}$

2.7.3 Check Device

Pressing the [D] key or clicking the Check Device button opens the check device options box.



This displays a list of the current hardware systems that are running on the current PC (see the following example). It is generally used for troubleshooting purposes if there is a communication problem with the existing system.

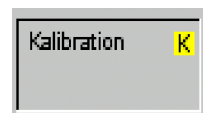
The most important entry in this list is the line:
ZAN 100(ZAN1310407022) : Running

This line makes sure, that the Flowhandy is connected to the USB port and active. The numbers may vary and depend on the particular device. However the word 'Running' has to be found at the end of this line.

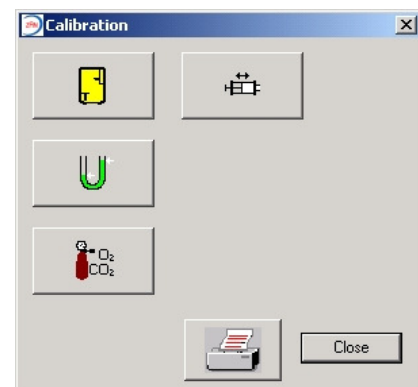


2.7.4 Calibration

Pressing the [K] key in the menu displays the calibration window.
(See also chapter 3.)



Select the desired programme with the mouse or the arrow keys and start it by pressing the [ENTER] Key.



2.7.5 Modify set-up

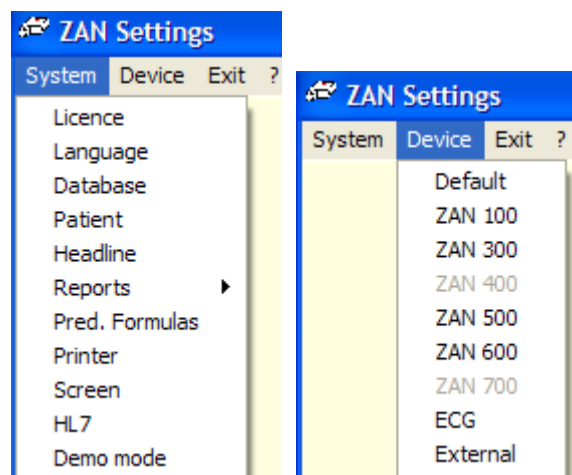
Pressing [alt/S] or selecting the Set-up button on the base level menu activates the Set-up window.



This Set-up window looks like this:

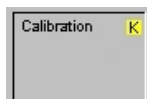


The Set-up Option enables you to set and change some of the programme settings including the following:



A detailed description of these settings can be found in the chapter „Set-up“ (A5) of this manual.

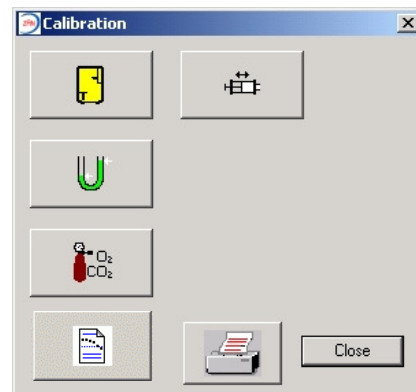
3 Calibration



Pressing the [K] key or selecting the button in the menu, displays the calibration window.

Depending on your licence and the included options, the window may have more or less symbols. Only active options are displayed)

Select the desired device to calibrate with the mouse or the arrow keys and start it by pressing the <ENTER> key .



3.1 Volume Calibration



Disinfection and use of the flow sensors can change the mechanical quality of the plastic membrane, on the inside of the flow sensor. The elasticity of the membrane fades and the difference in pressure in front of and behind the membrane will increase. This will affect the accuracy of the results.

To ensure optimum quality of measurements at any time, a calibration of the system can be performed with a calibration syringe.

Calibration of the flow sensor should be done at least after **50 Disinfections**, or it should be sent to ZAN for a service. If this is not possible, replace the flow sensor with a new one.

Using filters can reduce the number of necessary disinfections because the filter protects the flow sensor from contamination (also the filter protects the patient from contamination through the device).



3.1.1 Performing Volume Calibration

Make sure the flow sensor (including the adapter) is attached tightly to the calibration syringe. Verify that the piston of the syringe is completely inserted

The syringe volume (1.000L in this case) can be changed by selecting the [F4] icon.

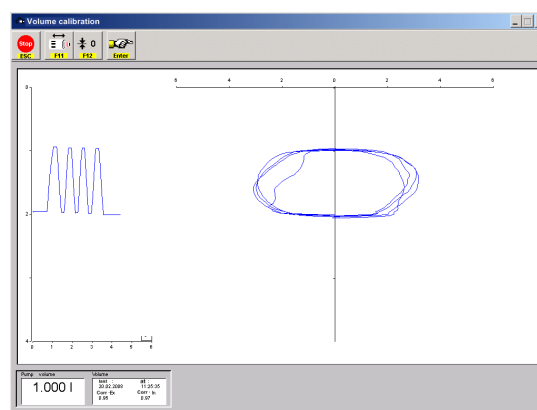
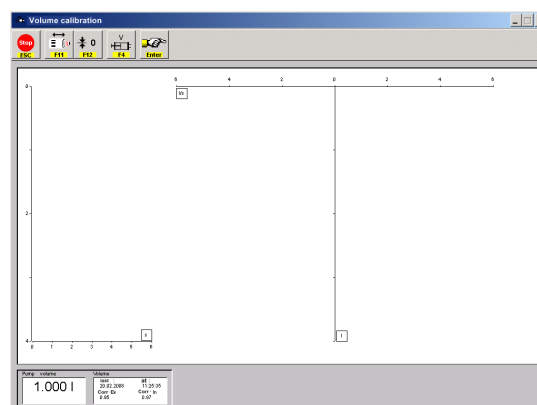


To start recording, press **Enter** and begin to pump steadily at a medium flow rate.

A well defined and constant volume of air is pumped through the flow sensor.

To ensure an identical volume is provided in every stroke, the syringe's piston has to be pushed in and pulled out as far as possible.

The recording of the volume/time curve is displayed.



After about 5 to 10 pump strokes, select **Enter** to end the calibration and begin the analysis. Results of the analysis are displayed in the following window. The calibration factors for each flow direction are stated.

RESULTS	
Parameter	
Korr Ex	0.99
Korr In	1.01

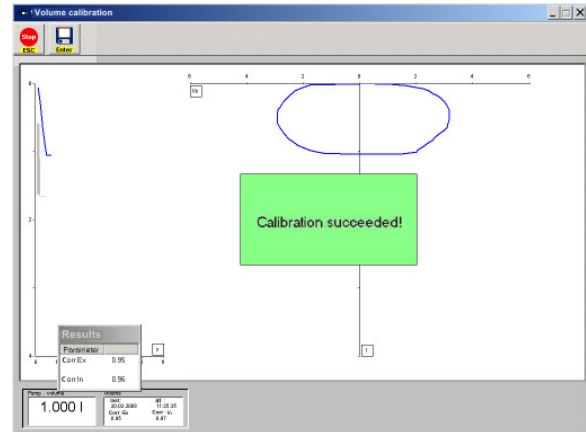
Important : The condition for a valid calibration is an absolutely precise calibration syringe. nSpire Health GmbH is able to provide appropriate devices

If the flow sensor works properly, a green field will be displayed in the calibration window.



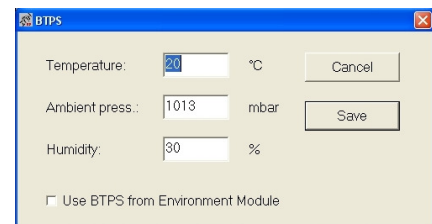
Select **Enter** to complete the calibration and save the calibration parameters.

If the difference between Corr In and Corr Ex exceeds 10% or if either calibration factor deviates from 1.00 by more than 6%, the flow sensor should not be used. A note to replace the flow sensor will be displayed in a window. After replacement of the flow sensor, the calibration process must be repeated.



Note: The flow sensor that failed calibration should carefully be cleaned and the holes of the flow sensor should be checked to verify they are not blocked. After drying the flow sensor, perform a new calibration. If the calibration fails a second time, the flow sensor should not be used.

After saving the calibration results, some devices will still prompt you to enter the ambient conditions.



Please adjust them and save them by clicking on the “Save” button. If the “Cancel” button is selected, the existing values will be used

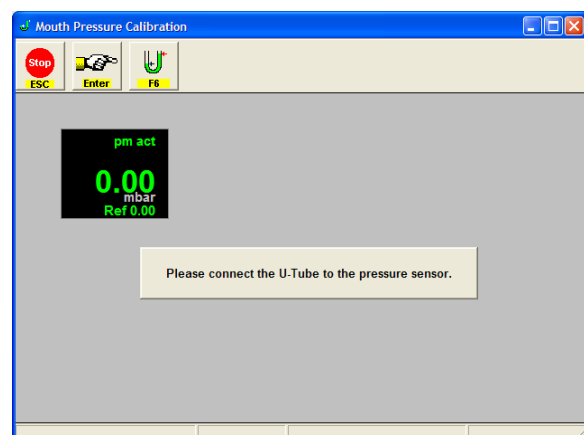
The actual ambient pressure is required here, not the pressure at sea level. If installed, check the ‘Use BTPS from Environment Module’ box. The temperature, pressure and humidity will be constantly updated.

3.2 Mouth Pressure Calibration

Mouth pressure calibration is performed using the shutter. A pressure transducer is employed to measure pressures inside the flow sensor. The mouth pressure measurement is achieved directly and is therefore generally stable for a long time.

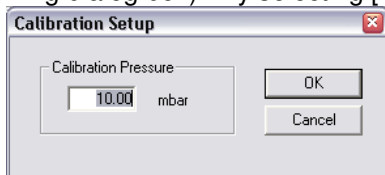
The accuracy of the mouth pressure transducer can be checked by using an appropriate pressure manometer (maximum ± 50 mbar) and through an access panel on the front of the device.

Note : Mouth pressure calibration should be performed during the annual system inspection.



To calibrate the mouth pressure transducer, click on the mouth pressure symbol (resembling a U-tube manometer) in the calibration window.

Calibrations are performed by introducing an accurate 10 mbar pressure change to the transducer (see the following dialog box). By selecting [F6], different calibration values can be entered or used.



Follow the instructions on the screen. First, attach the pressure manometer tube to the mouth pressure connection, located next to the connection cable on the backside of the flow sensor. Next, select **[Enter]** and the following dialogue will be displayed:

1/4: Set pressure = 0.0 mbar Start = [ENTER]



2/4: Set pressure = 10.0 mbar Start = [ENTER]

Use a 5ml syringe and the manometer to produce the reference pressure.

3/4: Set pressure = 0.0 mbar Start = [ENTER]

4/4: Set pressure = -10.0 mbar Start = [ENTER]

The results are displayed..

ERGEBNISSE	
Parameter	
Korr Pos	1.00
Korr Neg	1.01



Select **Enter** to save the calculated correction factors.

3.3 Body Plethysmograph Calibration



Important : The Body Plethysmograph Calibration should be executed at least once per day to ensure reliable function of the device.

Bodyplethysmograph calibration uses the latest results of the volume calibration (see above).

3.3.1 Performing the Bodyplethysmograph Calibration

To perform the Body plethysmograph calibration, the following steps must be taken.

After selecting the body plethysmograph calibration icon, the systems asks for the flow handy to be connected to the calibration socket and the door to be closed.



Please make sure that the Flow Handy is properly connected to the socket.



Close the door tightly. The metal plates of the door must snap in to the magnets of the frame with an audible click.

Important: If the magnet locks are not active, check if the emergency unlock button inside of the chamber is activated. Deactivate the emergency unlock by pressing the button again.

The computer recognises, if the doors are closed properly using the USB signals of the chamber and starts equalizing the pressure. This message shows up. After 15 seconds the process is complete and the message box closes automatically.

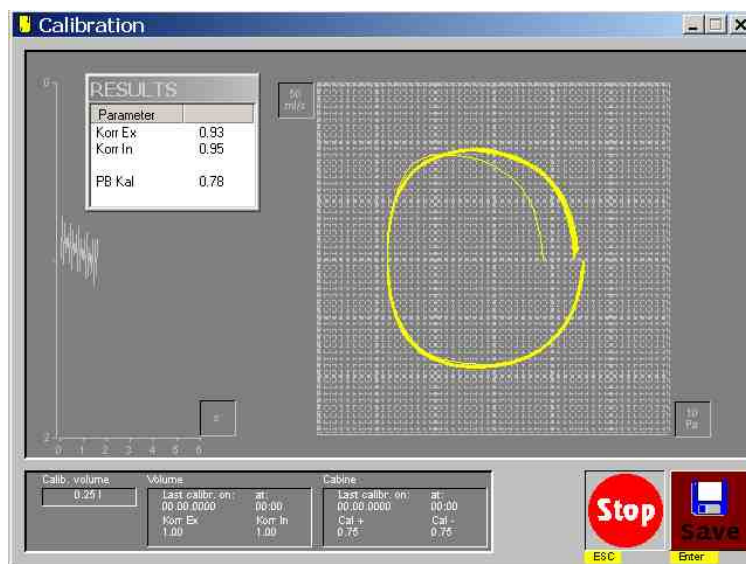


The calibration process starts within the next 5 seconds after the START symbol has been selected. The process is automated and user interaction is not required.

The calibration device underneath the chamber starts to pump with a characteristic sound.

A pump creates a sinusoidally shaped volume stream to the inside of the chamber. Measurement of the pressure inside the chamber and the volume stream creates a circular curve from which the chamber specific calibration factors are computed.

The user can see these curves on screen to control the process.



If the chamber is tight, the curve on the right should show an almost closed circular or oval shape.

The volume curve on the left should not show too much drift.

The calibration terminates automatically and the results are displayed in a small window. To save the

results, select the  icon or press the [ENTER] key. To abandon the results select the  or press the [ESC] key.

Don't forget to reposition the Flow Handy to its normal position before testing.

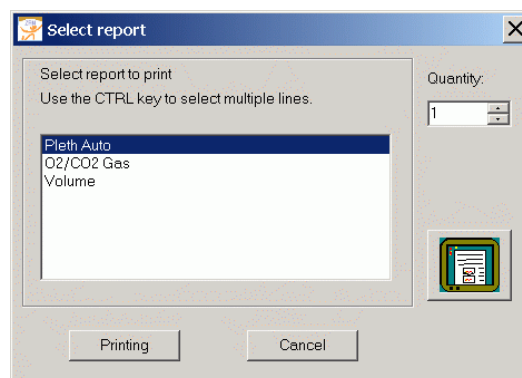
3.4 The Calibration Trend Reports



In order to control the quality of the calibrations, trend reports turned out to be very useful. To create a calibration trend report, press the  button in the calibration menu.

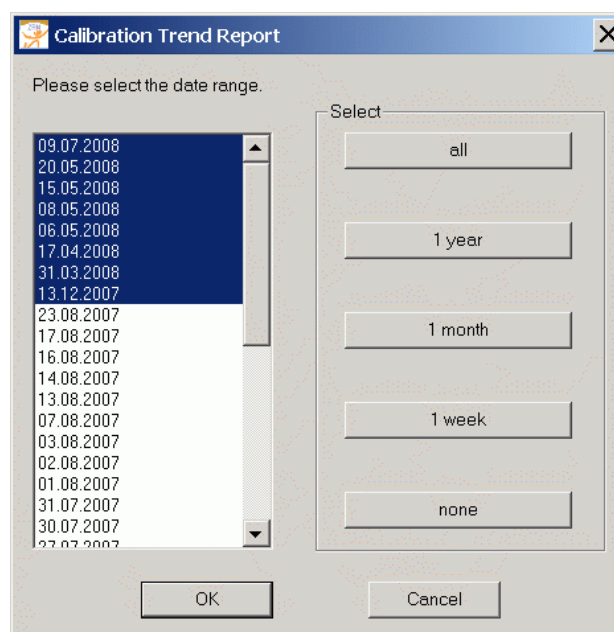
Select a particular report type from the list.

Selecting the preview button or the "printing" button leads to the date-range dialogue.



In the date – range dialogue select the period of time to be examined. Click on the desired date to select it. Select multiple dates by holding the 'control' key down during selection of dates. There is a list of shorthand buttons on the left side of the dialog for quickly select frequently used ranges. 'year', 'month' and 'week' select the current year, month or week. 'None' clears all selections.

[OK] starts the print out



After a few seconds, the print starts on your printer or, when preview was selected, the report is displayed on the screen.

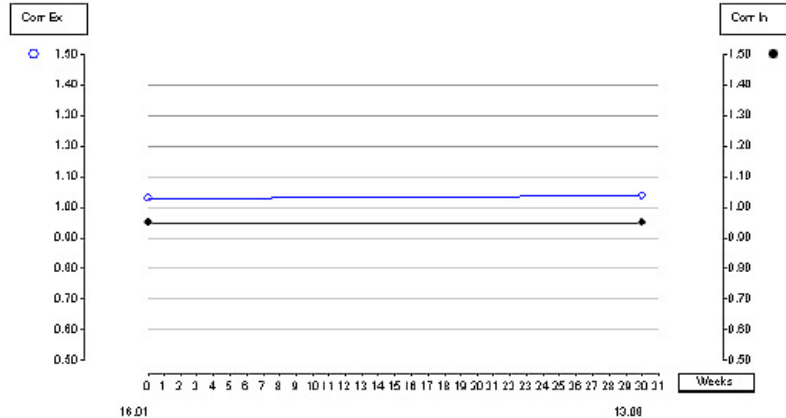


nSpire Health GmbH

Schlimpfhofer Str. 14
97723 Oberthulba

Tel.  +49 9736 8181-0  Fax. +49 9736 8181-20

Calibration Trend



Date	Corr Ex	Corr In
Limits	0.90 - 1.10	0.90 - 1.10
16.01.2008	1.040	0.960
13.08.2008	1.050	0.950

On closing this display, the programme returns to the main menu.

4 Measurement Procedures

4.1 SVC Measurement

SVC (Slow Vital Capacity) is a physiological test that measures how an individual inhales or exhales volumes of air as a function of time. The manoeuvres to measure the individual parameters are unforced, except at the point of reaching end expiration or end inspiration, where extra effort is required. The volumes that can be measured in spirometry consist of the following:



Abbreviation	Name	Definition
TV	Tidal Volume	The volume of air inhaled or exhaled during the respiratory cycle.
ERV	Expiratory Reserve Volume	The volume of air that can be maximally exhaled from a position of passive end-tidal expiration.
IRV	Inspiratory Reserve Volume	The volume of air inhaled from a position of passive end-tidal inspiration.
IC	Inspiratory Capacity	The volume of air inhaled from a position of passive end-tidal expiration.
VC	Inspiratory Vital Capacity	The maximal volume of air inhaled from the point of maximal exhalation.
VCex	Vital Capacity (expiratory)	The maximal volume of air exhaled from the point of maximal inhalation.

4.1.1 Measuring Separate Partial Volumes

The most important reference point of respiration is the Tidal Volume (V_t). At the end of tidal expiration, the retraction power of the thorax and the contraction power of the lungs are balanced.

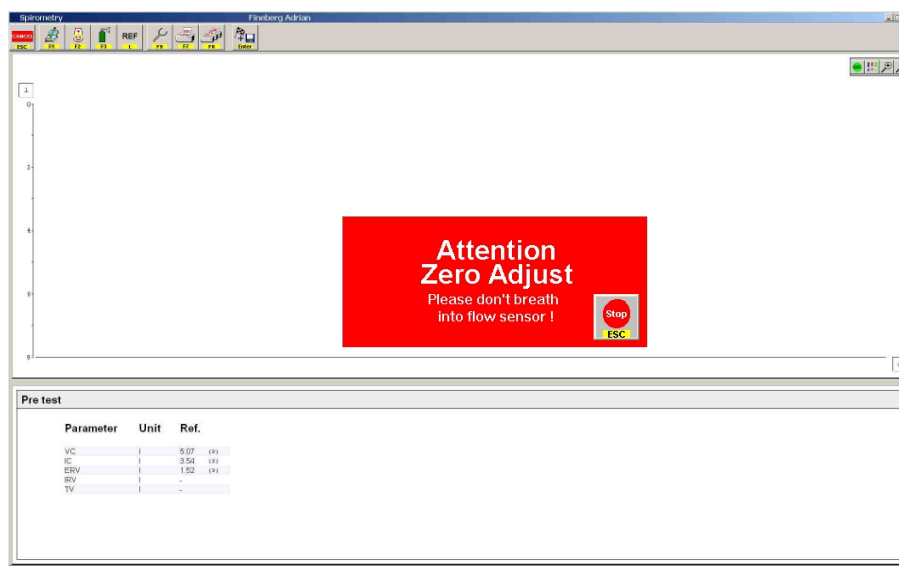
ERV is measured by having the patient exhale steadily and as deeply as possible. Some patients may take a small breath in before they exhale. This does not affect the results.

Once the patient has exhaled as deeply as possible, they should be encouraged to inhale maximally or as deeply as possible. This manoeuvre enables the calculation of the other spirometric parameters.

It is also possible to perform this measurement by getting the patient to inhale maximally from tidal breathing before exhaling as deeply as possible.

4.1.2 SVC Window

This window is displayed in the MEASURE mode after clicking on the spirometry symbol. After selecting the measurement, the following window is displayed:



Caution: During this measurement, the flow sensor will be zeroed, so it is important that there is no flow through the sensor. This process takes approximately 5 seconds.

4.1.2.1 Symbol Definitions



Select this icon or press the [ESC] key to stop the measurement and exit the programme.



Select this icon or press the [F1] key to display a dialogue box in which you can enter comments.



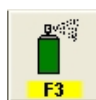
Select this icon or press the [L] key to select a reference value from another test for comparison.



Select this icon or press the [F2] key to define the user.



Select this icon or press the [F9] key to enter the test set up



Select this icon or press the [F3] key to select the medication.



Select this icon or press the [F7] key to print a single test result.



Select this icon or press the [F8] key to print out one or multiple templates



Select this icon or press the [F12] key to Check the results meet ERS/ATS 2005 Standards

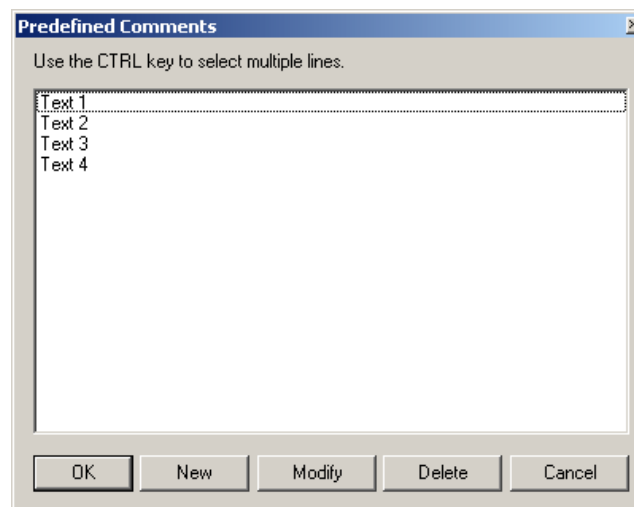
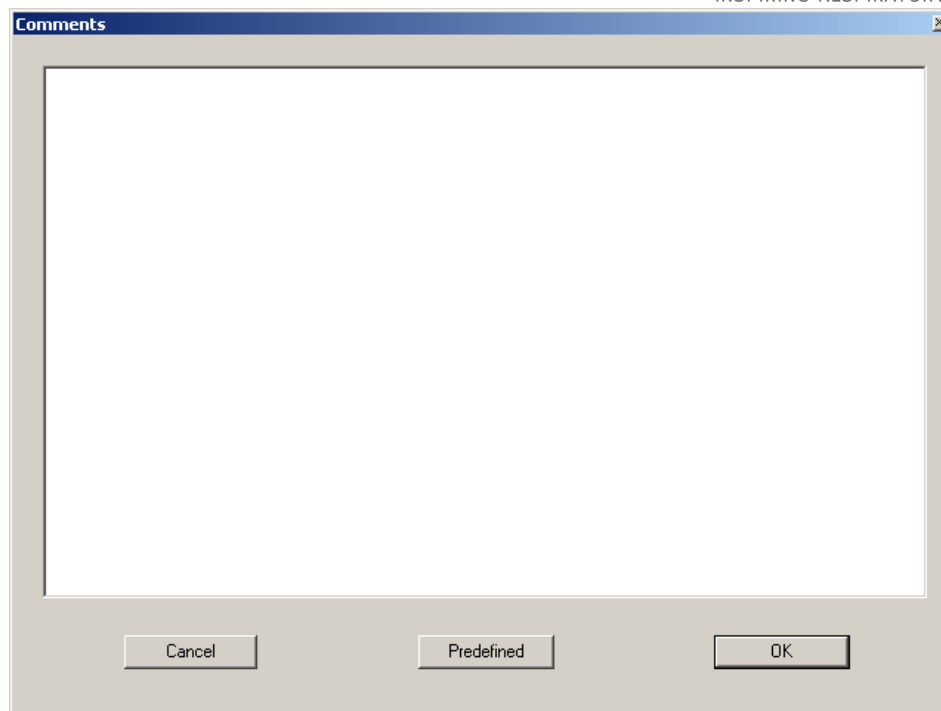


Select this icon or press the [Enter] key to save the measurement and exit module.

4.1.2.2 Enter Comments



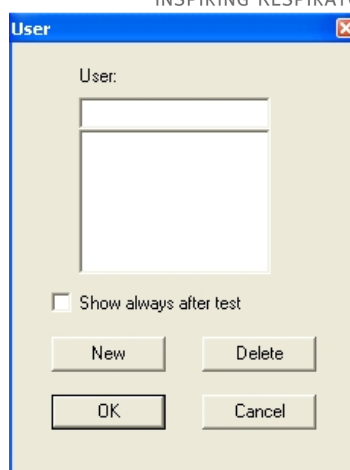
Selecting this icon or the [F1] key opens the comments dialogue box. Comments can be typed into the dialogue window and saved by pressing OK. By pressing the "Predefined" button, predefined comments can be inserted by using the second shown dialogue box. This dialogue box allows the user to create, modify and delete predefined comments. Each predefined comment consists of a full text and a short description, which is shown in the list box. Multiple predefined comments can be selected by pressing CTRL during selection.



4.1.2.2.1 Define User



Selecting this icon or the [F2] key enters the test operator's name. This is saved with the patient record. The user entered is applied to all tests that are carried out on the active patient. The user has to be defined for every new patient.



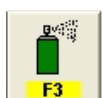
User name field

Pre-entered user name selection box

Display dialogue automatically at the end of the test

Clear User name field and insert new user name

4.1.2.2.2 Select Medication



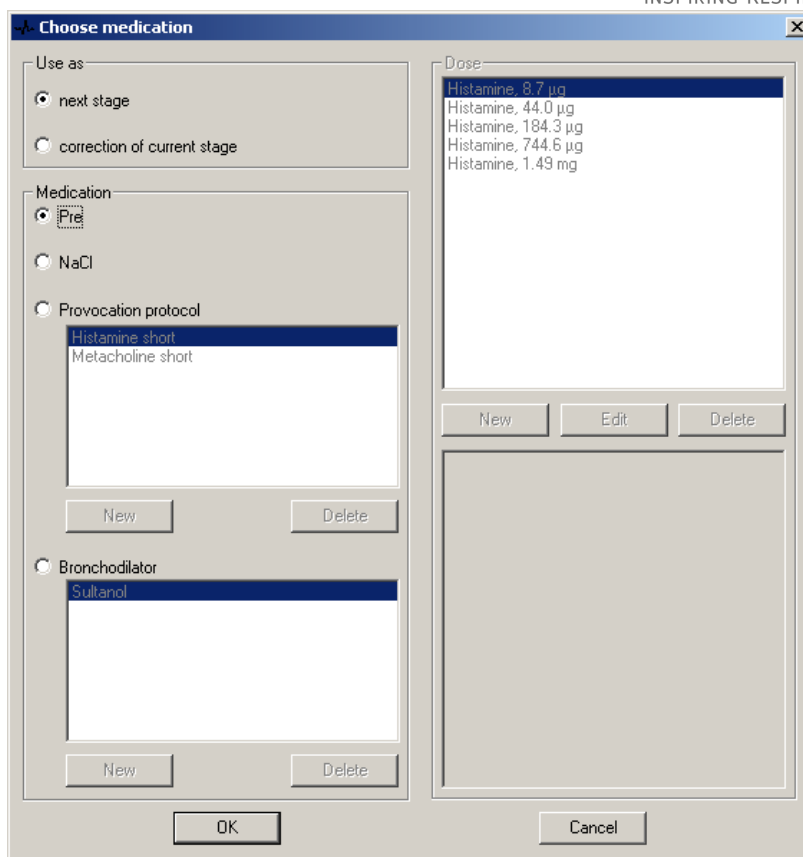
Selecting this icon or pressing the [F3] key selects the medication for the next stage.

The medication and dose given to the patient can be selected from the current medications entered into the system. The user has the choice to correct the medication for the current stage or to define the medication of the next stage.

On the left hand side of the window, the user is able to select the test stage. This can either be a Pre-stage without medication, a NaCl-stage, a dose of a provocation protocol or a bronchodilator (Post-Stage).

For a dose, the user needs to first select a protocol from the list. It is also possible to create a new protocol (see below). As soon as a protocol is chosen, the possible doses of this protocol are shown in the list box on the right hand side. (If the dialogue box is opened during a provocation protocol, the protocol in use and the next dose are selected automatically). Again, the user has a choice to create, edit (see below) or delete doses. On the bottom right hand side of the window, the user is shown how to do the provocation to get to the selected dose. This includes concentration, nebuliser and count of nebulisations. For the count of nebulisations, the computer calculates the difference between the target dose and the dose currently in the lung (0 if not cumulative).

For bronchodilators, it is possible to either select none of the medications in the list box or one of those listed. Bronchodilators can be created or deleted.



Choose medication

Use as:

- ☒ next stage
- ☐ correction of current stage

Medication:

- ☒ Pre
 - ☐ NaCl
 - ☐ Provocation protocol
 - Histamine short
 - Metacholine short
- ☐ Bronchodilator
 - Sultanol

New Delete

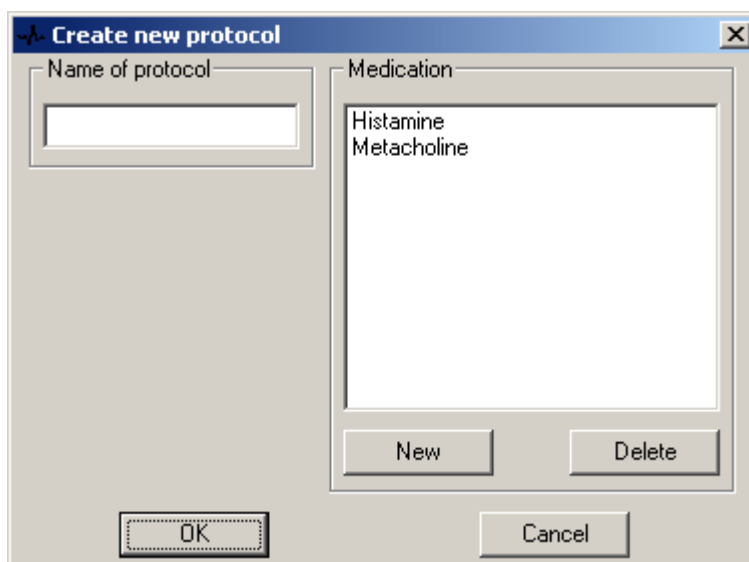
Dose:

- Histamine, 8.7 µg
- Histamine, 44.0 µg
- Histamine, 184.3 µg
- Histamine, 744.6 µg
- Histamine, 1.49 mg

New Edit Delete

OK Cancel

With the dialogue box shown below, new provocation protocols can be created. The protocol needs to be given a unique name. The medication that is used in the protocol needs to be chosen from the list. Medications can be deleted as long as they are not being used by other protocols. New medications can also be created.



Create new protocol

Name of protocol:

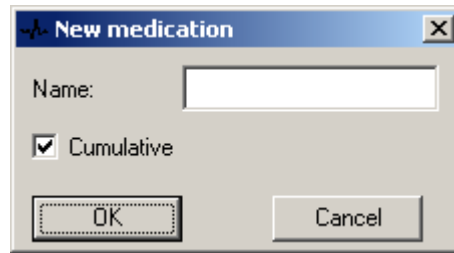
Medication:

- Histamine
- Metacholine

New Delete

OK Cancel

When creating a new medication, the dialogue box below appears. It allows the user to enter the name of the medication as well as if the medication is cumulative.



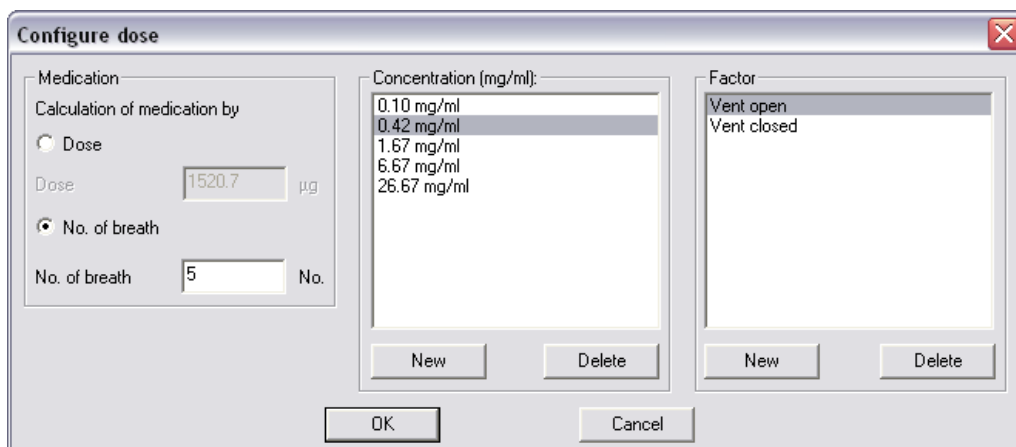
New medication

Name:

☒ Cumulative

OK Cancel

The dialogue box shown allows the user to create or edit a dose. It has an entry field for the dose (read only when editing an existing dose) as well as a list box for the concentration and the factor to be used. Again, elements can be added to or deleted from the list boxes (as long as they are not being used by another protocol).



Configure dose

Medication

Calculation of medication by

☐ Dose

Dose μg

☒ No. of breath

No. of breath No.

Concentration (mg/ml):

- 0.10 mg/ml
- 0.42 mg/ml
- 1.67 mg/ml
- 6.67 mg/ml
- 26.67 mg/ml

New Delete

Factor

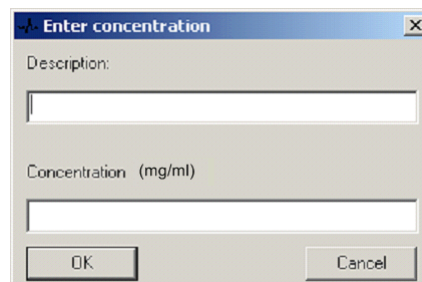
- Vent open
- Vent closed

New Delete

OK Cancel

Since the ATS '5 breath protocol' requires 5 nebulizations, an additional way to define the protocol exists calculating the dose by the number of breath's. Simply check the 'No. Of breath' radio button and enter the desired count of breath to calculate the doses.

To enter a new concentration, use the dialogue box shown below. The description is the text that is shown in the list box and allows the physician to determine the correct dose concentration. The concentration is entered in mg/ml.



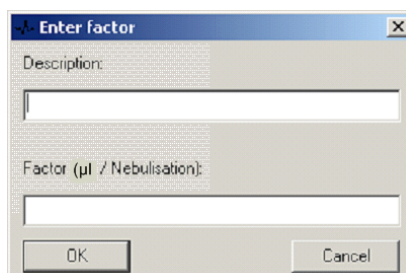
Enter concentration

Description:

Concentration (mg/ml)

OK Cancel

To enter the factor of the nebuliser, use the dialogue box below. The dialogue box allows the entry of a description (for instance the name of the nebuliser) as well as the volume (in μl) that is nebulised per nebulisation.



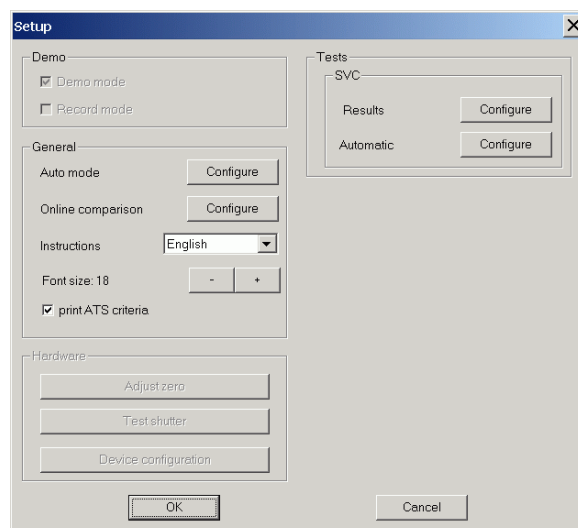
The 'Enter Factor' dialog box has a title bar with a close button. It contains two text input fields: 'Description:' and 'Factor (μl / Nebulisation):'. At the bottom are 'OK' and 'Cancel' buttons.

4.1.2.3 System Set-up



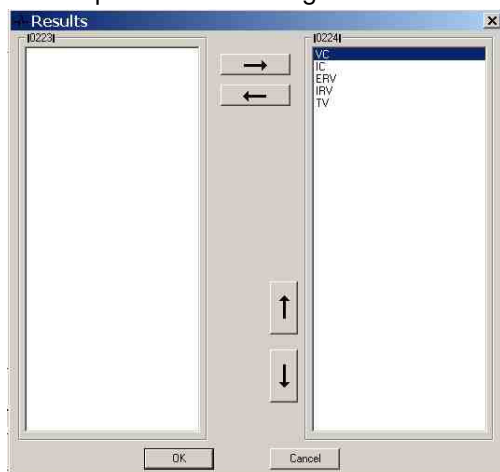
Selecting this icon or the [F9] key enables the configuration of the spirometry programme and the selection of system components.

The Set-up screen has three active sections: Test Set-up, General Settings and Hardware Set-up.



The 'Setup' dialog box is divided into three main sections: 'Demo', 'General', and 'Hardware'. The 'Demo' section has checkboxes for 'Demo mode' (checked) and 'Record mode'. The 'General' section includes 'Auto mode' and 'Online comparison' (both with 'Configure' buttons), a language dropdown set to 'English', a font size of 18 with '+' and '-' buttons, and a checked 'print ATS criteria' checkbox. The 'Hardware' section has buttons for 'Adjust zero', 'Test shutter', and 'Device configuration'. On the right, the 'Tests' section shows 'SVC' with 'Results' and 'Automatic' sub-sections, each with a 'Configure' button. 'OK' and 'Cancel' buttons are at the bottom.

Test Set-up allows you to select the results shown after the test and to set up automatic saving of the results. When you click on the configure keys you get the following screen graphics.



The 'Results' dialog box shows a list of test results on the right: 'VC', 'IC', 'ERV', 'IRV', and 'TV'. There are navigation arrows (left, right, up, down) and 'OK' and 'Cancel' buttons at the bottom.

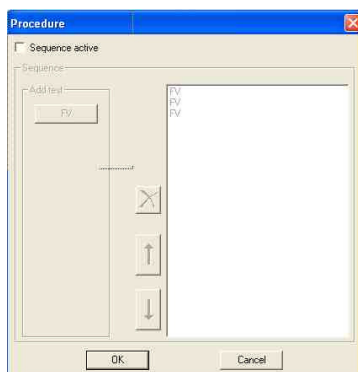
This screen allows you to set up the number of baseline breaths before performing the test.

It allows the choice of an inspired or expired breath as the first breath of the test, and offers you the opportunity to enter the elapse time, after which the test is automatically stored.



The 'Automatic' dialog box has a checked 'Automatic' checkbox. The 'Procedure' section includes 'Start after breath' (set to 5) and 'Auto save' (checked). Below is a text field '10.0' followed by '\$ after manoeuvre'. The 'Manoeuvre' section has radio buttons for 'Ex - In' (selected) and 'In - Ex'. 'OK' and 'Cancel' buttons are at the bottom.

The General mode allows you to set up an automatic sequence, for example the sequence shown below allows you to set up 3 consecutive FVC tests.



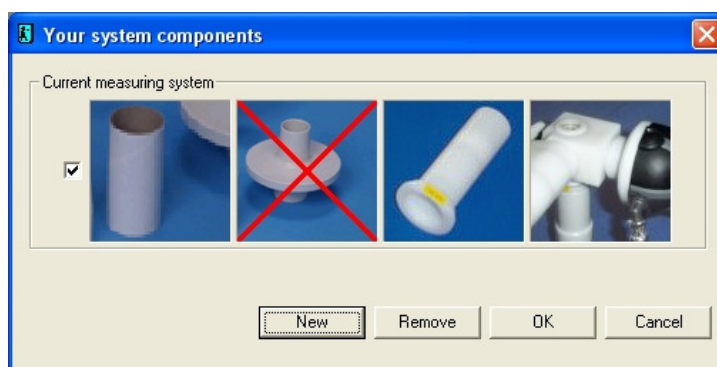
The general setting gives online comparison settings, language settings and auto mode settings

The online comparison settings allow you to compare to best test, to reference, or to nothing. This corresponds to the test that is shown in red when performing a test.



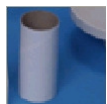
The current language options include English, German, French and Spanish. This language setting only affects the instruction texts during measurement. This feature allows test instructions to be seen in alternative languages for patients who need instructions in a different language.

The Hardware Set-up allows you to reset the shutter, zero the flow sensor and set up the component for the test as seen below.

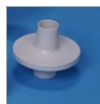


Symbol Definitions

By double clicking with the left mouse button it is possible to enter one of the option menus and select the appropriate component.



Select from mouthpiece options.



Select from filter options.



Select from Flow sensor options.

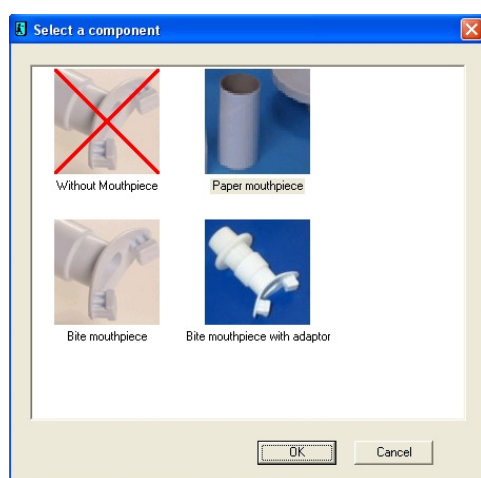


Select from shutter options.

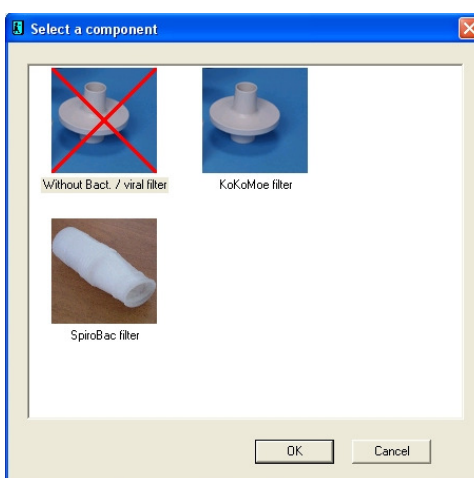
To view the current configuration, hold the cursor over the appropriate option field.

Default mouthpiece options

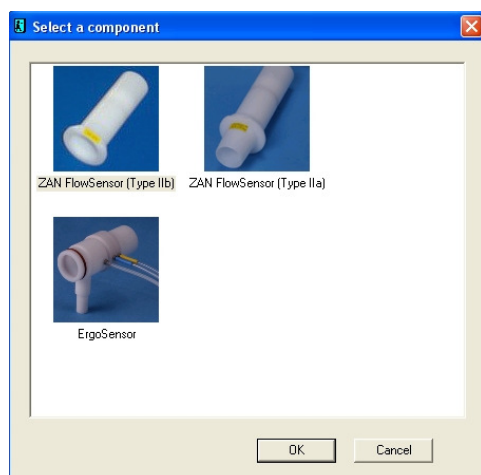
Without Shutter



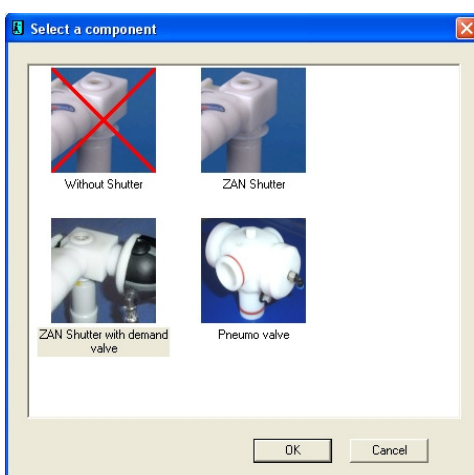
Default filter options



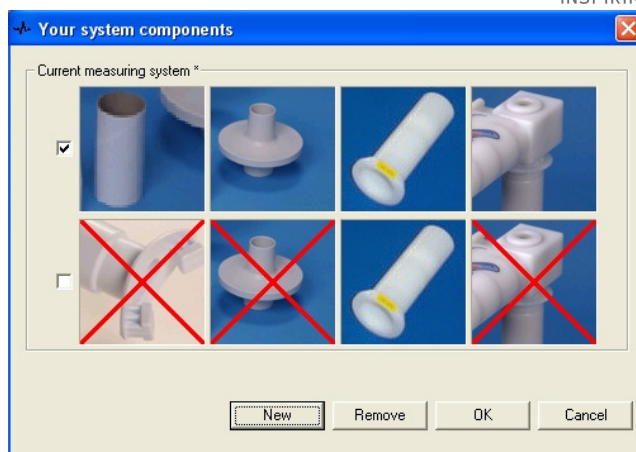
Default flow sensor options



Default shutter options



Save multiple configurations for easy selection by pressing the [New] button.



4.1.3 Performing SVC Testing



Select this icon (located at the right hand side of the screen) to start the measurement.

4.1.4 Symbol Definition



Select this icon or press the [ESC] key to end the test without saving.



Select this icon or press the [Enter] key to save the measurement and exit.



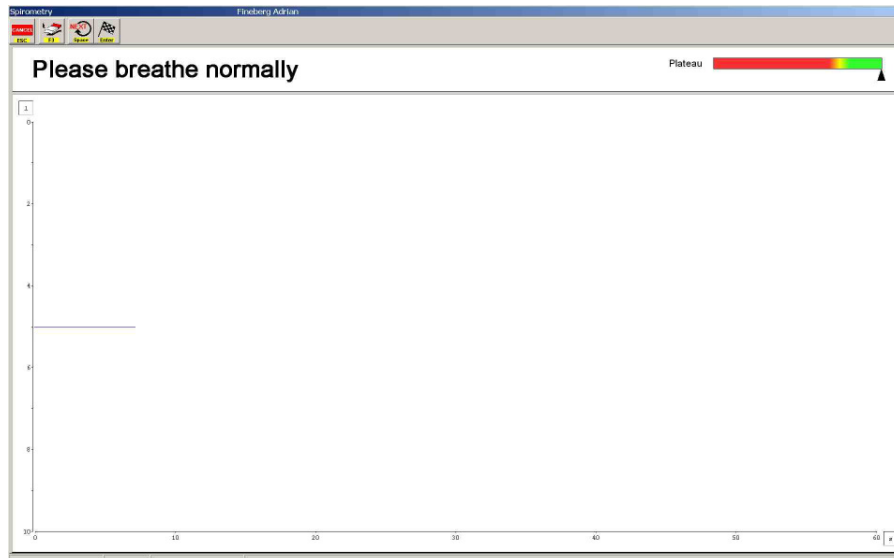
Select this icon or press the [space] key to save the measurement and start a new measurement.

The volume trace is displayed on the graph as a blue line and scrolls from left to right. The patient should use a nose clip and form a tight seal around the mouthpiece with his or her lips. The patient should breathe normally through the mouthpiece. The following example is an Ex-In manoeuvre.

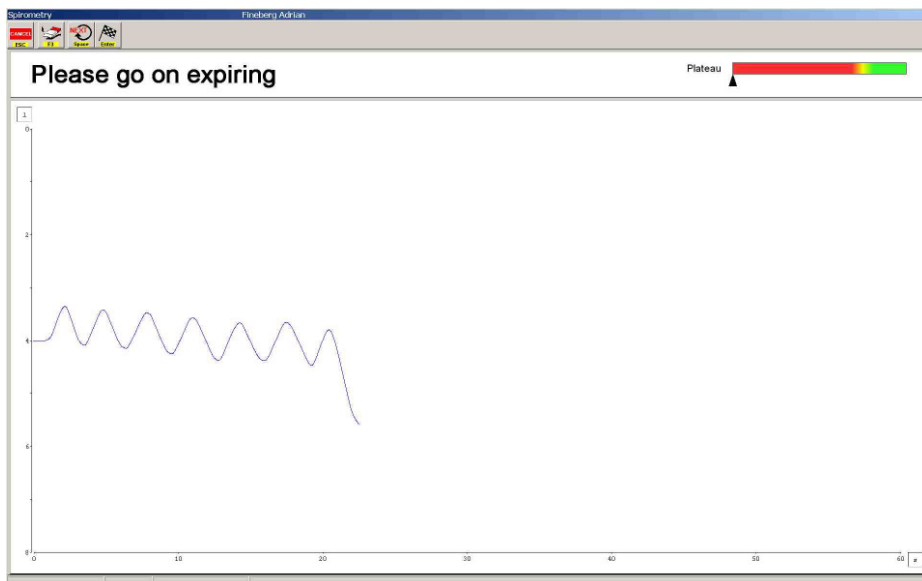
These have the same structure, but with inhalation instead of exhalation.



If the trace is unsatisfactory, the measurement can be re-started by pressing the [F3] key. This deletes the results and continues the measurement.

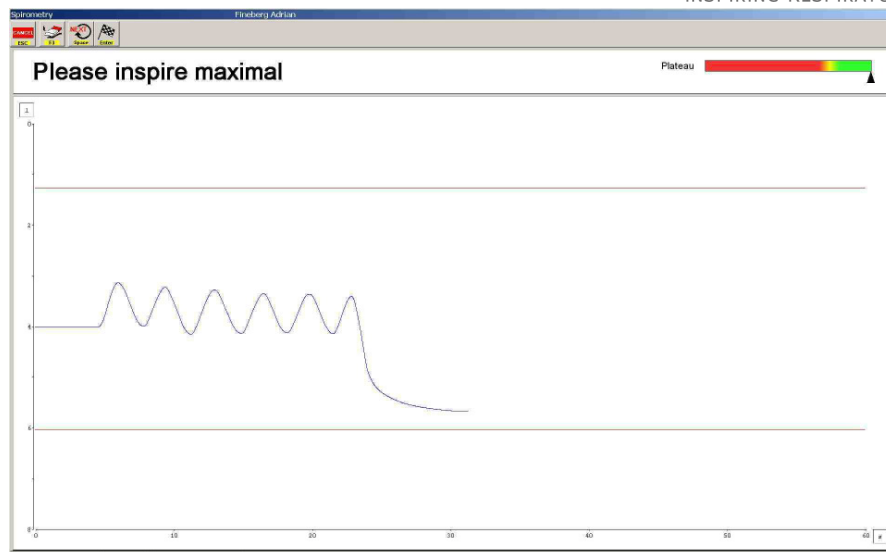


To determine the tidal volume, the patient should breathe normally through the mouthpiece. If the automatic mode is selected in the set-up (after the predetermined number of breaths) the computer instructs you to expire maximally. The patient should be encouraged to exhale slowly for as long as possible.

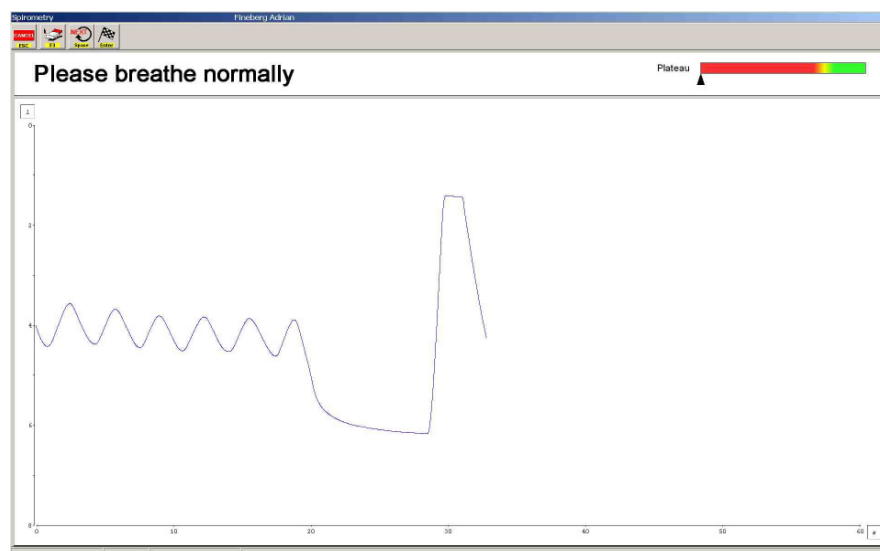


When the lungs are completely empty, the computer will instruct you to perform a deep steady inhalation. During this procedure the plateau slide bar gives an excellent indication of whether or not the patient is close to the end of their breath.



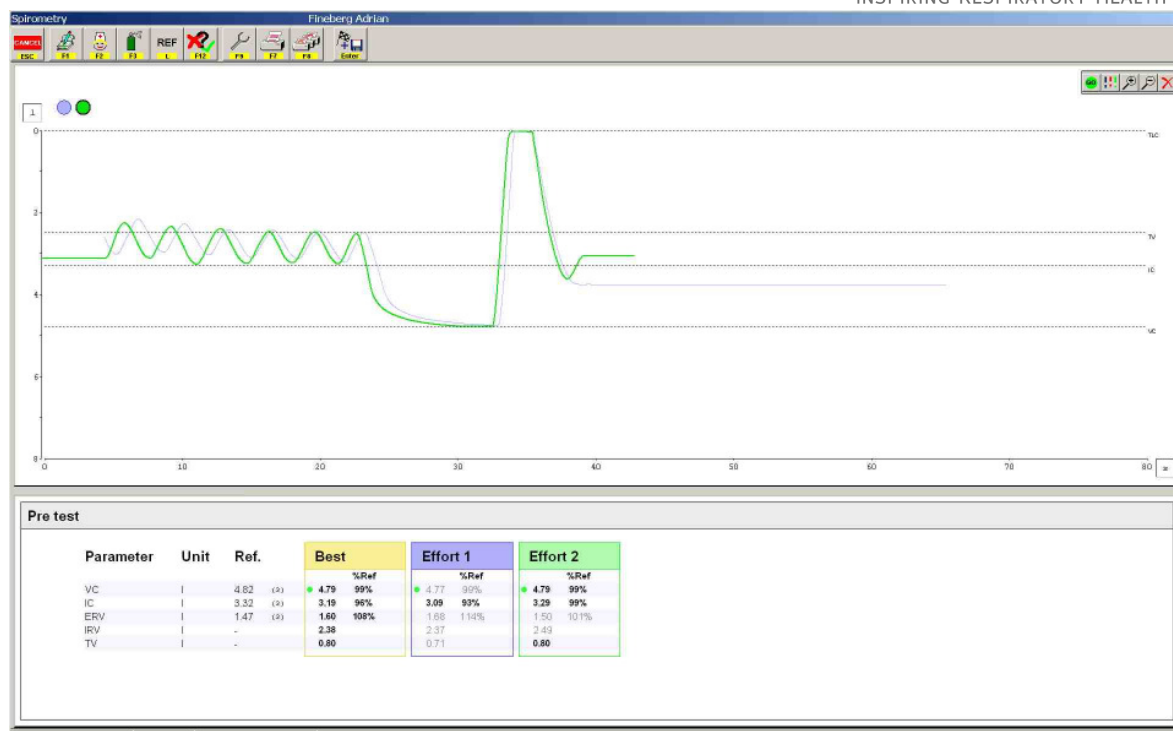


At the end of the inhalation, the patient can return to normal tidal breathing.



If a test is available for online comparison, two lines will show the corresponding vital capacity. The first manoeuvre that touches or crosses a line moves both lines, so that the curve will not cross this line. By having this visual help during the test, the user can easily determine whether the effort is reproducible with respect to the online comparison.

Additional VC manoeuvres can be performed when the patient is rested and ready. Once sufficient manoeuvres have been made, press  to end the test and display the results. The following screen will be displayed at the end of the test.



The efforts are colour coded and the tabular data is shown at the bottom of the screen. You can choose to view the graphics as a volume/time trace or as a bar graph by clicking the bar graph symbol on the right hand side of the screen. To zoom in and out, use the magnifying glass icons



The computer automatically selects the best effort to be reported for this stage. This is shown by the highlighted coloured dot. You can change the computer decision by left-clicking on a different coloured dot.

ATS/ERS have provided criteria for the acceptance of the test. The computer will automatically determine whether the criteria for acceptance are met. If an effort is not acceptable, this is shown by a red cross over the corresponding coloured dot. To remove the effort from the selection process right-click on the coloured dot.

The fulfilment of ATS-criteria is also visualised by the result table. Green and red dots show for each parameter that is defined by ATS, whether the criteria were met or not. This includes the criteria for acceptance as well as those for reproducibility (only shown when more than one effort performed).

The result window also has a column called "Best". This column shows the results that are reported for this stage. The results of the single efforts that are taken into account for the creation of the "Best" are plotted in bold. The value that is reported is either from the selected effort, the maximum of all accepted efforts, the mean of all accepted efforts or recalculated. The standard methods are according to ATS.

4.1.5 SVC Guidelines

In many cases, the patient is nervous before the measurement, resulting in erratic tidal breathing. The patient's respiration should be corrected by verbal encouragement to give a more stable baseline for the rest of the measurement.

To ensure accurate results, the patient should be encouraged to exhale and inhale completely. This is demonstrated by a plateau at the end of each part of the manoeuvre.

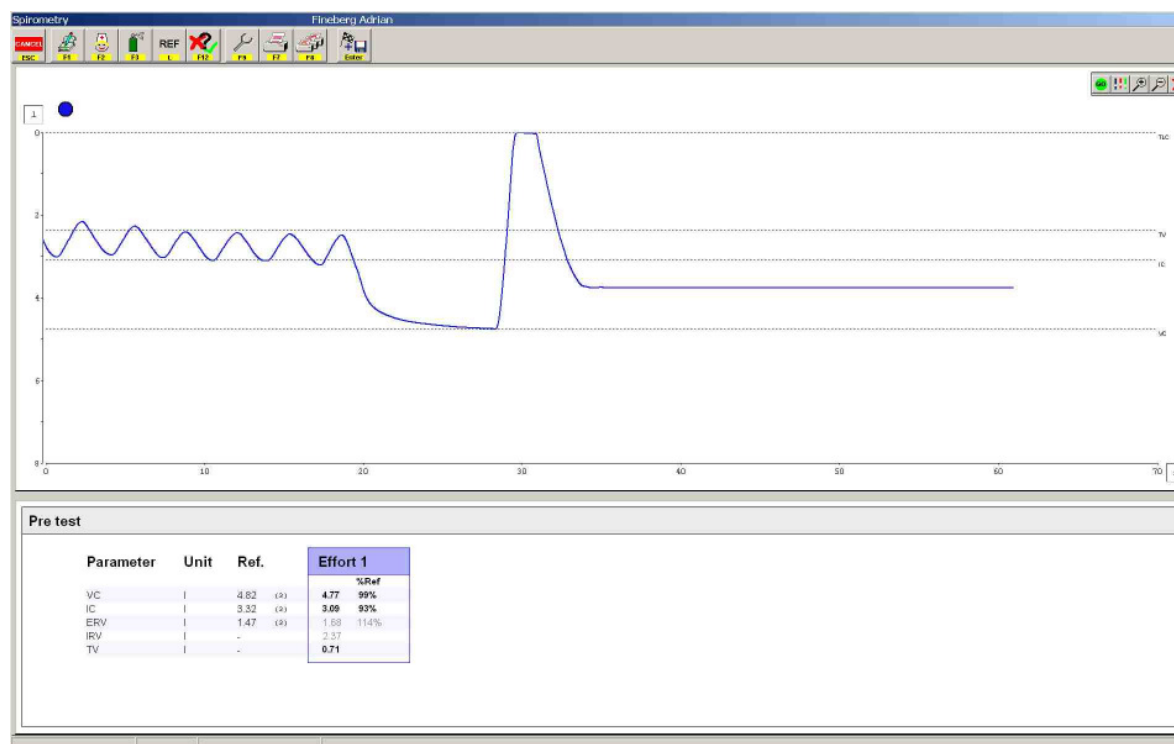
If there is an air leak from the patient at the mouthpiece or the patient comes off the mouthpiece, the measurement should be repeated to achieve correct calculations of the partial volumes.

4.1.5.1 Co operation

To ensure accurate and reproducible results, the patient should be encouraged throughout the measurement. It is recommended that the test be repeated until three acceptable manoeuvres have been obtained. Optimum co operation will result in reproducible results.

4.1.5.2 Adjusting Lung Volume Sub-Divisions Manually

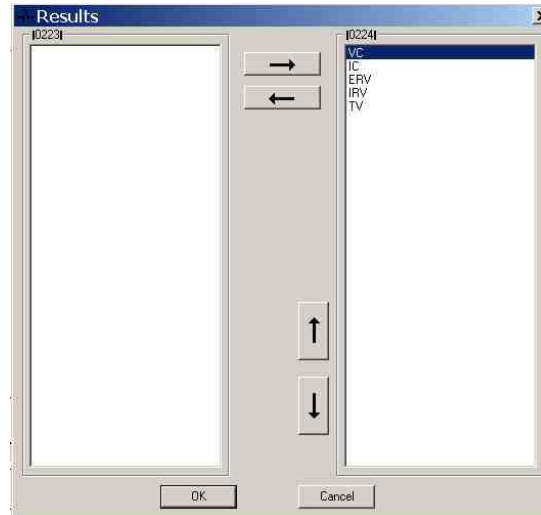
The position of the lung volume sub-divisions can be changed and the values re-calculated by selecting one of the lines with the mouse and holding down the left mouse button. To illustrate the line was selected with the mouse; it is shown as a thicker green line.



4.1.6 Parameter Selection



To alter the parameters displayed in the results table, open the set-up function using the  button.



From the “All Measurements” list, you can select the parameters you want to view in the results table. These parameters will be inserted into the “Selected Measurements” list.

4.1.6.1 Symbol Definition



Moves the selected parameter into the “Selected Measurements” list (right window).



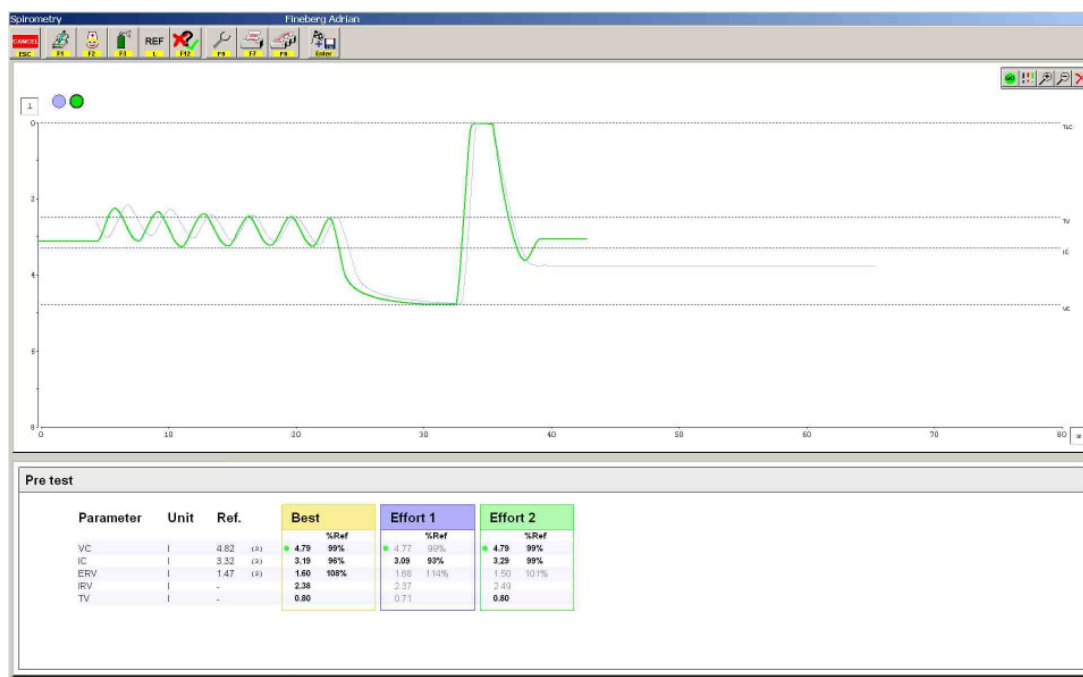
Removes the selected parameter from the “Selected Measurements” list (right window).



Moves the parameter up or down in the “Selected Measurements” list (right window).

4.1.7 Viewing Measurements

In the “View” mode, all measurements (or only selected ones) can be viewed.



The software has two different views in which it can show the test results. The first is the Effort View. This view shows all efforts of one stage and allows the user to correct efforts by the use of tangents to determine the effort that represents the stage. The second view is the Slot View. This view shows the “Best” effort of each stage. This viewing mode allows Pre/Post comparisons as well as trending for provocation tests.

If in the Effort View screen, the name “Effort View” will be shown in the grey header of the result window. To move to the Slot View, left-click within the result window.

To change from Slot View (see picture below) to Effort View, left click within the result window on the column of the stage you want to see the efforts from. While in Effort View the coloured dots are used to select the best curve, set the acceptance of an effort, or highlight multiple curves for better visual comparison.

■

REF
L

Select reference test [X]

Test date

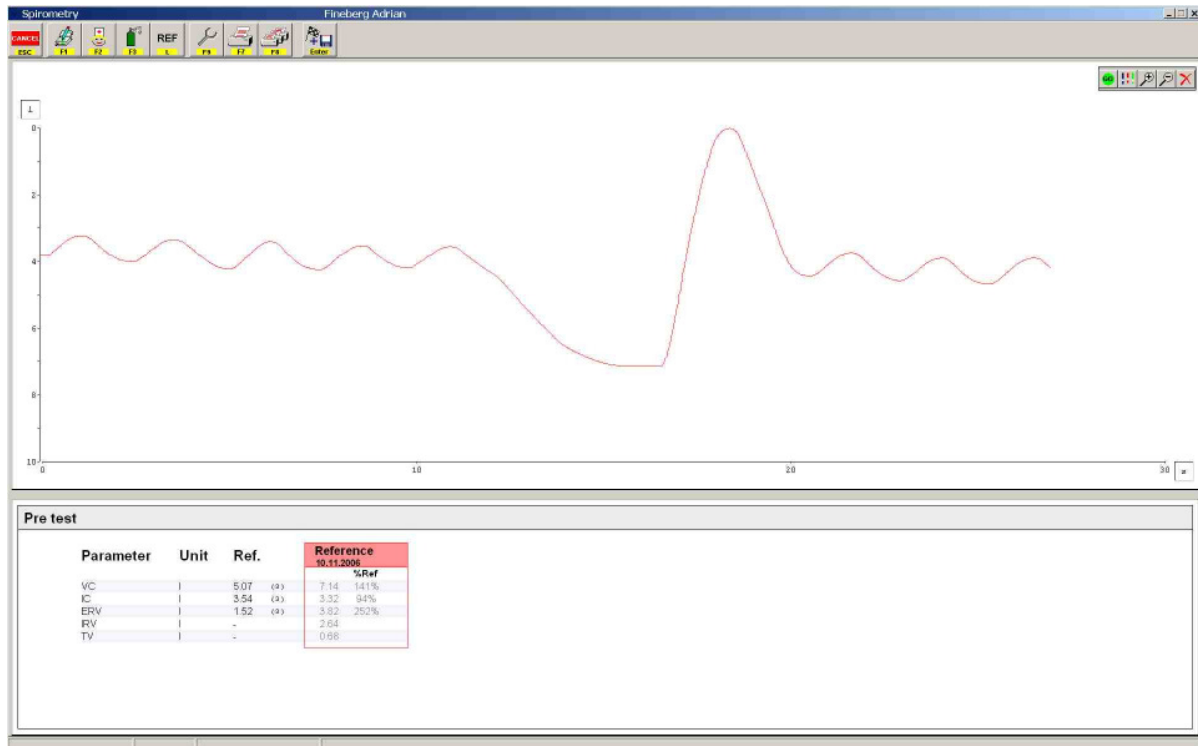
- No reference
- 10.11.2006**
- 21.11.2006

Test

Phe test

OK Cancel

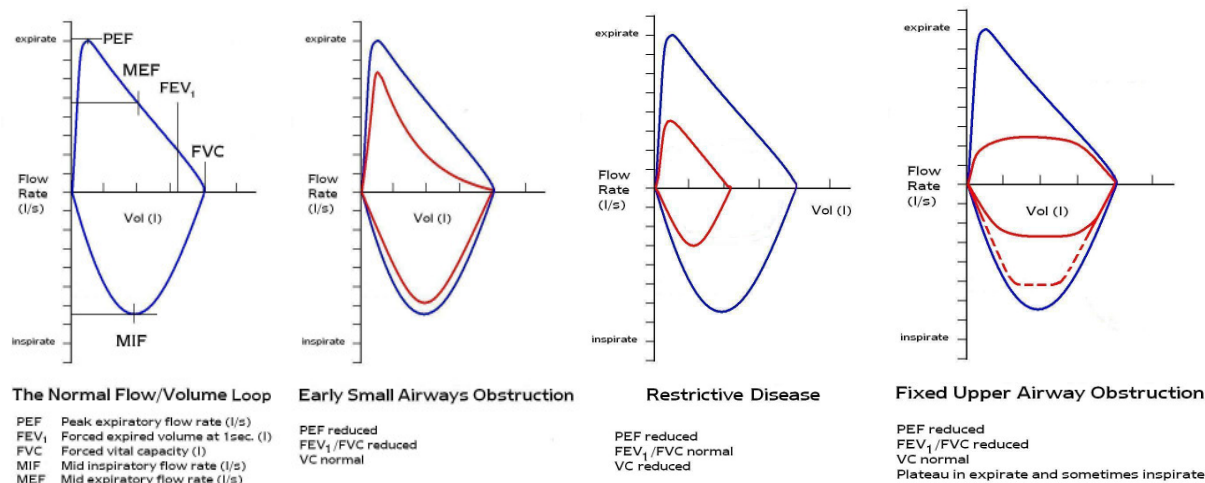
You will then see the comparison of current data to the reference selected.



4.2 Flow/Volume Measurement

4.2.1 Definition Of A Flow/Volume Measurement

The Flow/Volume loop is the recording of the flow rate plotted against the volume. The flow/volume loop shows the lung's reaction during maximum flow speed. According to the constitution of the lung tissue, the expiratory flow is more or less strongly limited. Typical loops will occur according to specific lung constitutions.

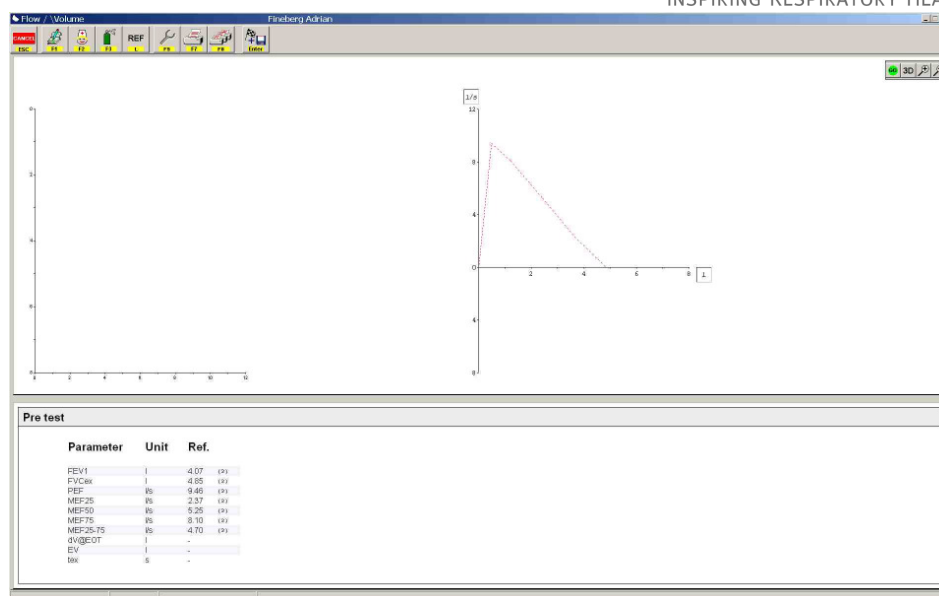


4.2.2 Important Measurement Parameters

Short name	Name	Meaning
FVC	Forced vital capacity.	Maximum expiratory volume with maximum flow speed.
FEV1	Forced expiratory volume within the 1st second of exhalation.	Volume that can be forcefully exhaled within the first second.
PEF	Peak expiratory flow.	Maximum flow speed during exhalation.
MEF 75	Flow at 75% of expiratory volume.	Flow speed after 25% of exhalation.
MEF 50	Flow at 50% of expiratory volume.	Flow speed after 50% of exhalation.
MEF 25	Flow at 25% of expiratory flow.	Flow speed after 75% of exhalation.
FEV1/FVC	Ratio between FEV1 and FVC.	Obstruction parameter.
AEX	Area underneath the expiratory curve.	Equivalent to FEV1.
PIF	Peak inspiratory flow.	Peak flow during inhalation.
MI[F5]0	Flow at 50% of inspiratory volume.	Flow speed after 50% of inhalation.

4.2.3 Flow/Volume Screen before Measurement

This window is displayed in the MEASURE mode after clicking on the Flow/Volume symbol.



4.2.4 Symbol Definitions



Select this icon or press the [ESC] key to stop the measurement and exit the programme.



Select this icon or press the [L] key to select a reference value from another test for comparison.



Select this icon or press the [F9] key to enter the test set-up



Select this icon or press the [F7] key to print a single test result.



Select this icon or press the [F12] key to check that results meet ERS/ATS 2005 Standards



Click the go icon to start the test



The button V/t switches graphics to the Volume/Time graph (button only available, if not F/V and V/t on the screen at the same time)



Select this icon or press the [F1] key to display a dialogue box to enter comments.



Select this icon or press the [F2] key to define the user.



Select this icon or press the [F3] key to select the medication.



Select this icon or press the [F8] key to print out one or more templates.



Select this icon or press the [Enter] key to save the measurement and exit module.



The 3D icon switches to view graphic in 3D the magnifying glass icons zoom in and out



The 2D icon switches graphics into a 2D view



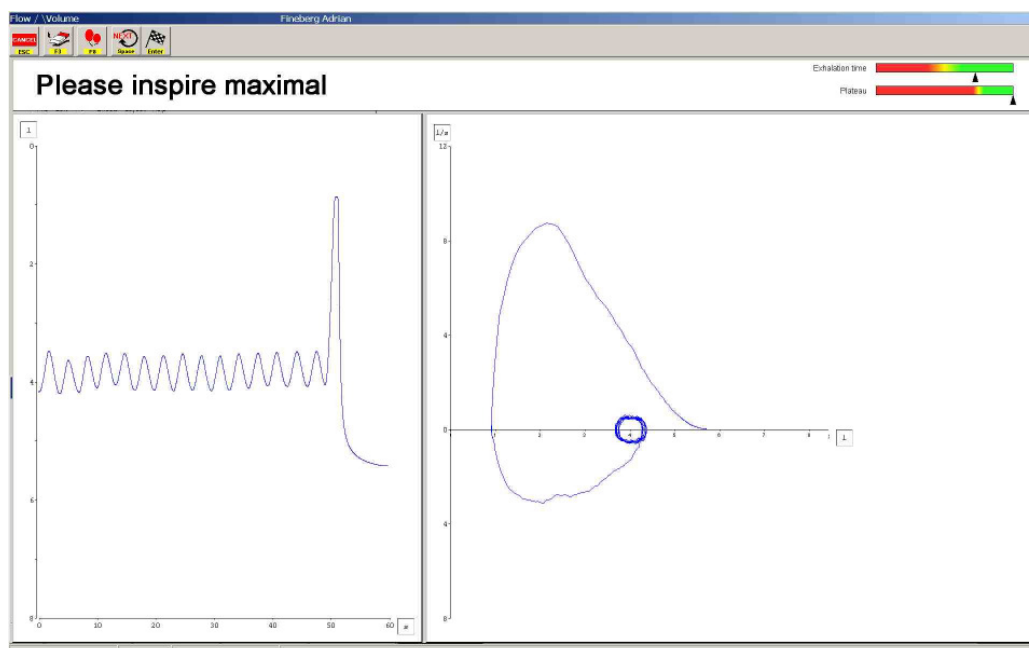
The button F/V switches graphics to the Flow/Volume graph (button only available, if not F/V and V/t on the screen at the same time)

4.2.5 Performing a Flow/Volume Measurement

On the screen the recording of the volume/time curve displays in the left part of the window. The flow/volume loop (on the right) displays when respiration starts.

Caution: It is important that the patient uses a nose clip and forms a tight seal around the mouthpiece.

The patient should perform several tidal breath's before executing a the FVC manoeuvre. Using the delete key F3, the recording can be re-started and the screen can be cleared.



Symbol Definitions



Select this icon or press the [ESC] key to stop the recording without saving any data.



Select this icon or press the [Enter] key to stop recording the measurement.



Select this icon or press the [F3] key to delete previous recordings.



Select this icon or press the [space] key to save and perform another effort.



Select this icon or press the [F8] key to switch on incentive graphics.

Every click on this icon will change the screen to a new incentive graph.

4.2.6 FV Measurement Guidelines

A flow/volume measurement with meaningful results demands the optimum co-operation of the patient. It is important that the patient inhales and exhales the complete volume of his or her lungs with maximum flow speed.

You have to distinguish between an inspiratory and an expiratory F/V curve. To measure the inspiratory curve, the patient has to slowly exhale the complete volume of his or her lungs in order to inhale as fast and as deeply as possible afterwards. In order to measure the expiratory flow, the patient has to exhale as fast and as deeply as possible after maximum inhalation.

To guarantee a complete exhalation, it is recommended to exhale for at least 6 seconds. During the measurement, a time bar will be displayed in the upper right of the screen. It starts to increase with each exhalation and changes colour from red to green after 6 seconds. When this occurs, the patient

should inhale again. Also in the right hand side of the screen, is the plateau graphic which is an indication of flow nearing zero. This gives information to the technician on the quality of the manoeuvre performed by the patient.



4.2.7 Co-operation

To judge the patient's co-operation, the maximum exhalation should be repeated 3 times. It is important that the patient exhales as fast and as deeply as possible. With optimum co-operation, all curves will be positioned closely on top of each other and have a nearly identical form.

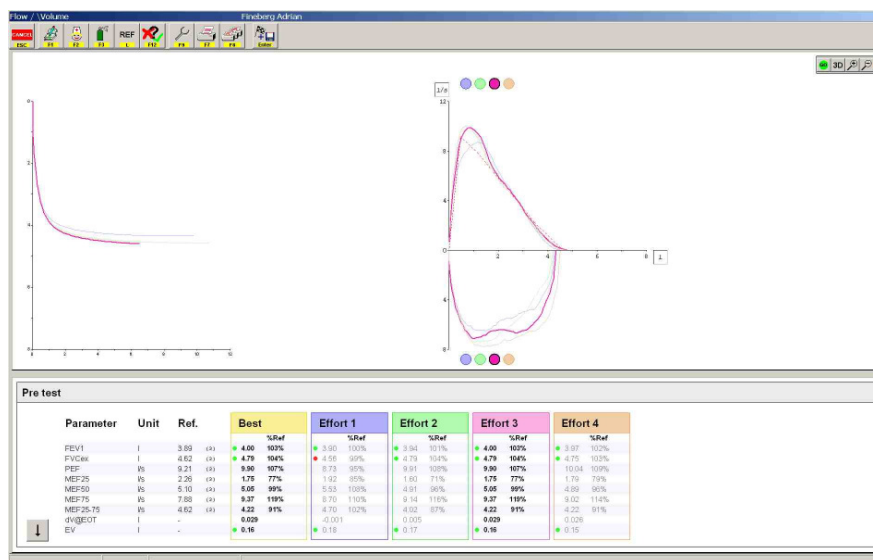
The curve's form will be pointed if the patient's co-operation was at an optimum. See picture below.

To exhale the whole volume, the patient must exhale for at least 6 seconds. The measurement curve must slowly merge into the base line.



To finish the measurement and display the results, press the **Enter** icon

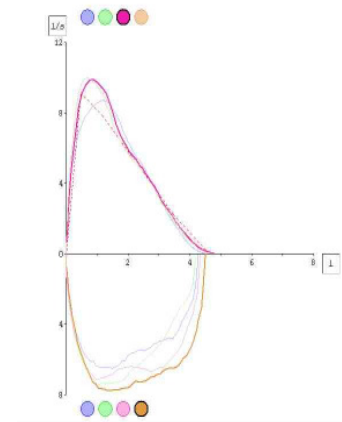
4.2.8 Flow/Volume Screen after Measurement and result edit



The four efforts are colour coded and the computer selects the best result. In this example, effort 3 is highlighted. You can mix and match the flow volume inspired and expired according to the ERS /ATS 2005 guidelines. Simply click on the coloured circle you wish to see for the final report (for both the top and bottom of the graphic). This example shows effort 3 for the expired loop combined with effort 4 for the inspired loop.

According to ATS there are criteria for the acceptance of the test. The computer will automatically determine, whether the criteria for acceptance are met. If an effort is not acceptable, this is shown by a red cross over the corresponding coloured dot. In order to remove a loop from the selection process you simply right click on the related coloured dot.

The fulfilment of ATS criteria is also visualised by the result table. Green and red dots show for each parameter that is defined by ATS and whether the criteria were met or not. This includes the criteria for acceptance as well as those for reproducibility (only shown when more than one effort performed).



The result window has a column called "Best". This column shows the results that are reported for this stage. The results of the single efforts that are taken into account for the creation of the "Best" are plotted in bold. The value that is reported is either from the selected effort, the maximum of all accepted efforts, the mean of all accepted efforts or recalculated. The "Best" efforts are determined using ATS/ERS standards.

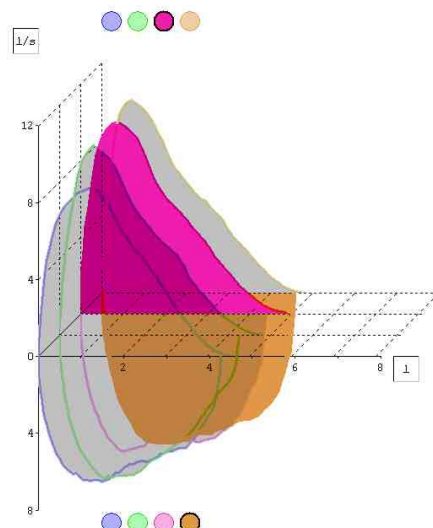
4.2.9 Different views of graphics

You can view the flow volume loops in the conventional 2 dimensional view or the newly available 3 dimensional view. The 3D view gives the added value of depth when looking at a number of loops

together. To change the view, click on the 3D icon.



You will get the following display



To return to the conventional view click the 2D icon in the top right hand side of the screen

4.2.10 Quality guidelines



Select this icon or press the [F12] key to see if efforts conform to quality standards



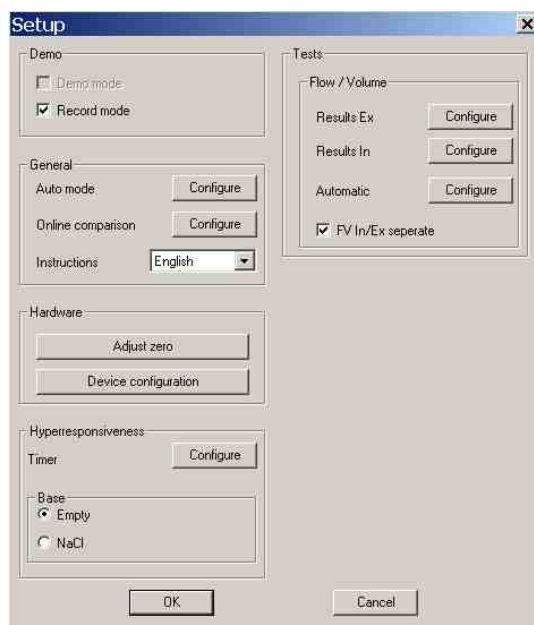
4.2.11 Set-up



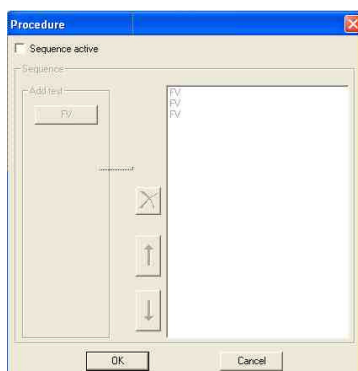
By clicking on the  icon, you enter the test Set-up Menu

There are five sections of the Set-up menu: Demo Set-up, General Set-up, Hardware Set-up, Test Set-up and Hyper-Responsiveness Set-up.

The Demo Set-up mode is for sales purpose only, and should not be connected to the computer.



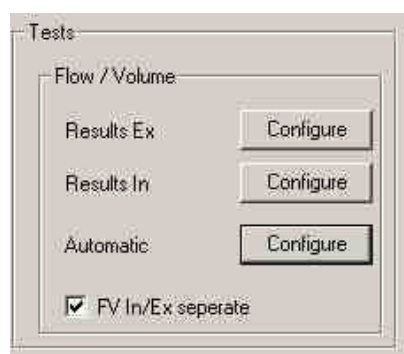
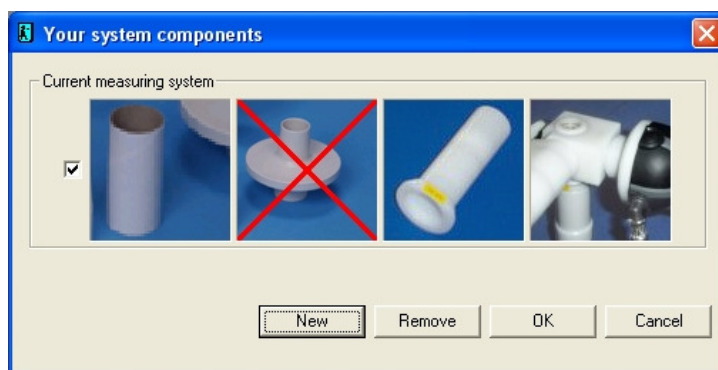
The General Set-up mode allows you to set up an automatic sequence, for example, if you always want to perform 3 FVC tests in a row, you can simply set up the sequence as shown below



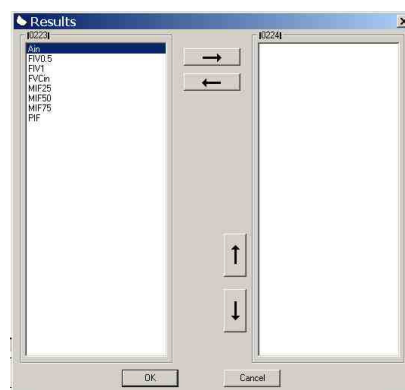
The “Set-up online comparison” dialogue allows you to configure result comparisons. Please see the dialogue box below for comparison options.



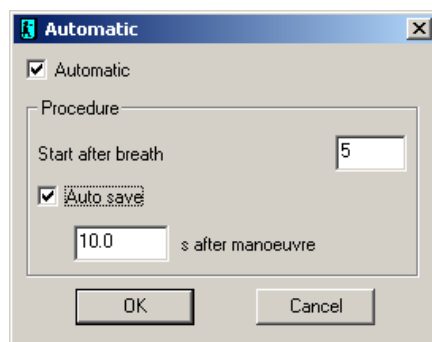
The hardware configuration allows you to reset the zeroing point of the flow sensor and configure the set-up of the device from a filter/mouthpiece perspective.



This allows you to set the parameters you want to see after the test is performed from both the expired and inspired results, and the order of the results displayed on the screen.



You can set the Automatic option, which allows you to automatically save the results of each test. In this way you can concentrate on the patient instead of having to push the enter key to save the trace at the end of the test

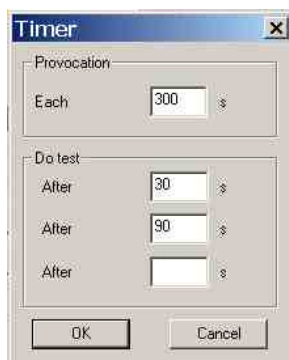


Finally, the  tick box allows you to remove the ability to split the inspired and expired portion of the loop.

Under the Hyper-Responsive set-up you can configure the timer for the bronchial challenge program.

The timer is helpful for the user to do the provocations and after a defined time period, keep the cumulative effect of the medication. According to ATS/ERS, provocations should be performed every 5 minutes.

The test timers allow the defining of up to three time points, after the provocation, that the efforts should be performed. The ATS/ERS recommends that these efforts be performed at 30 and 90 seconds (respectively).



4.2.12 Animation Programme

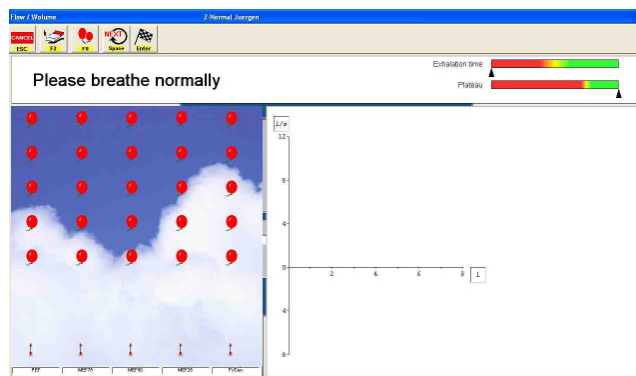


Select this icon **F4** or [F8] to display the animation programme. With each click, the animation selection changes.

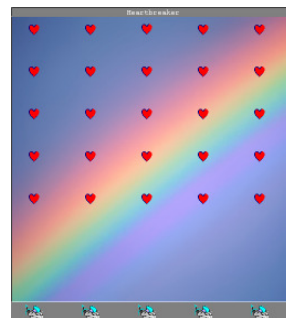
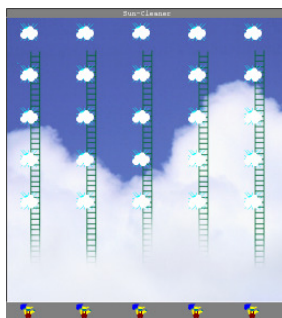
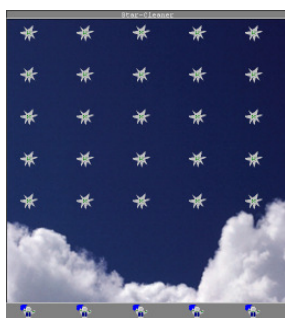
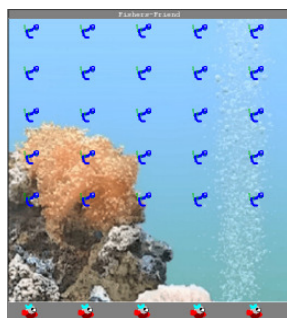
The animation programmes are meant to motivate patients, especially children, to help perform a maximum effort (for example, to make all the balloons burst).



Note: With each click on the **F4** icon, the animation selection changes.



Additional animation selections follow:



There are various motives.. Select the motive which your patient likes best.



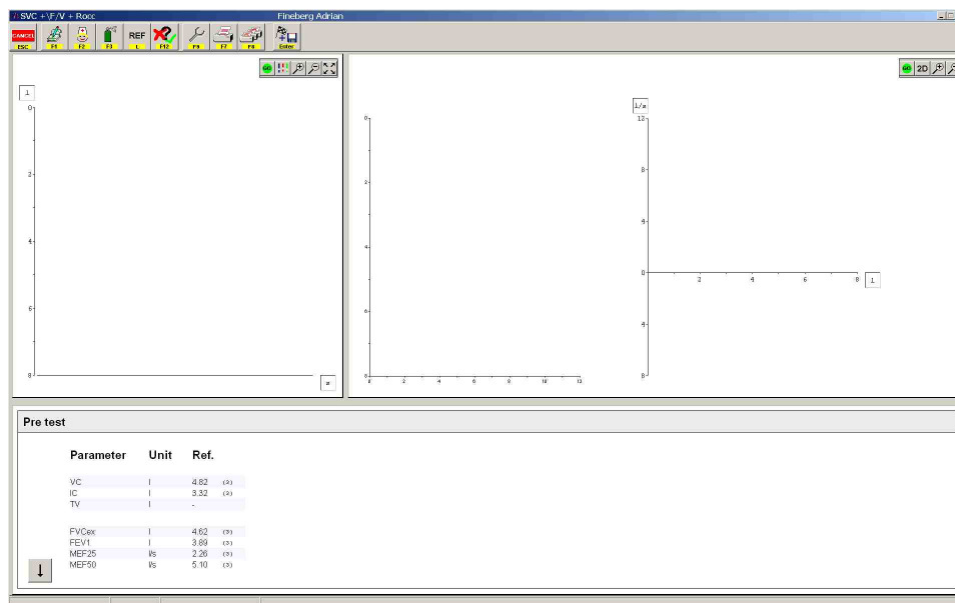
To finish the measurement and display the results, press the **Enter** icon

4.3 Combined SVC and F/V Measurement

4.3.1 Combined SVC and F/V Measurement Window before Measurement



Selecting the icon in the MEASURE mode enables the measurement of SVC as well as F/V measurement with one single procedure.



Symbol Definitions



Select this icon or press the [ESC] key to stop the measurement and exit the programme.



Select this icon or press the [L] key to select a reference value from another test for comparison.



Select this icon or press the [F9] key to enter the test set-up



Select this icon or press the [F7] key to print a single test result.



Select this icon or press the [F12] key to check that results meet ERS/ATS 2005 Standards



Click the go icon to start the test



Select this icon or press the [F1] key to display a dialogue box to enter comments.



Select this icon or press the [F2] key to define the user.



Select this icon or press the [F3] key to select the medication.



Select this icon or press the [F8] key to print one or more templates.



Select this icon or press the [Enter] key to save the measurement and exit the module.

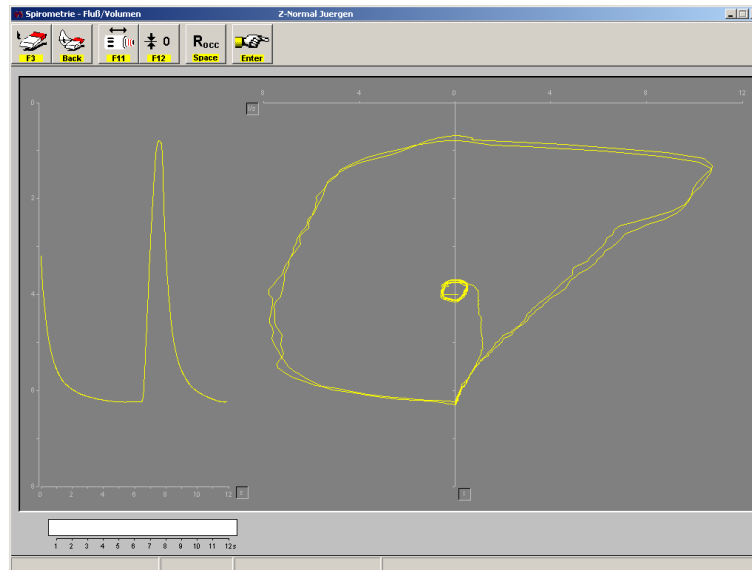


The 3D icon switches to view graphic in 3D the magnifying glass icons zoom in and out

First the SVC Test is performed. Please refer to the SVC Chapter for detailed information.

Directly after the slow inspiration the forced expiration is performed. Please look for detailed information in the F/V chapter.

4.3.2 Airway Resistance Measurement (ROCC)



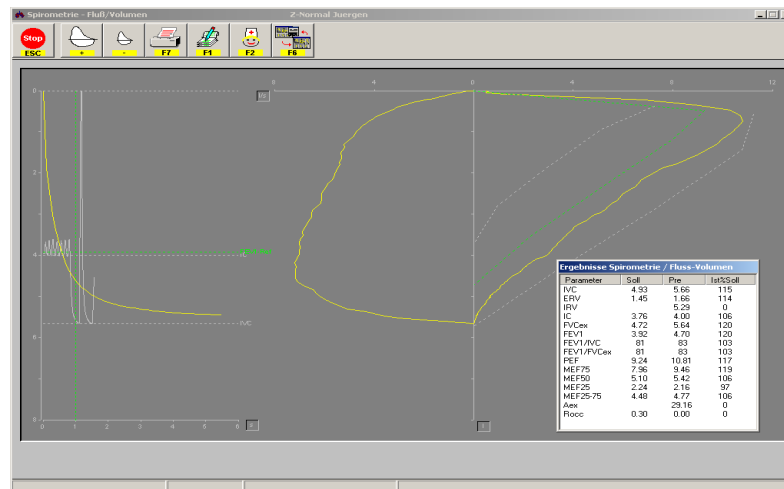
If your ZAN device is equipped with a valve (shutter), the respiratory flow can be interrupted during tidal breathing by pressing the space bar during a spirometry measurement.

If the pressure that was caused during the interruption is measured and divided by the flow that was caused after opening the valve, the flow resistance can be measured.

The last five measured interruptions will be analysed and displayed in the list of results.

If the valve does not close with the next exhalation after pressing the space bar, the patient was probably breathing too slowly. Either the breathing depth or the breathing rate must then be slightly increased.

4.3.3 Spirometry, Flow / Volume Screen after Measurement



Symbol Definitions



toggles the results table on and off.



saves the measurement.

Parameter Selection

By double clicking on the results table, a dialogue window is displayed with a selection of parameters. From the list of parameters, you can select the parameters you want to view in the results table. These parameters will then always be shown in the results table.

Look in the paragraph "Parameter Selection" in chapter "SVC" for detailed instructions.



The results and the measurement will be saved after pressing the **Enter** key.

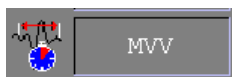
4.4 Measurement of the Maximum Voluntary Ventilation (MVV)

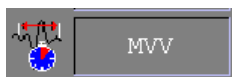
Maximum Voluntary Ventilation (MVV) is the maximum volume of air a subject can breathe over a specified period of time (12 seconds for normal subjects). This value is normally corrected to 1 minute and is expressed in l/min.

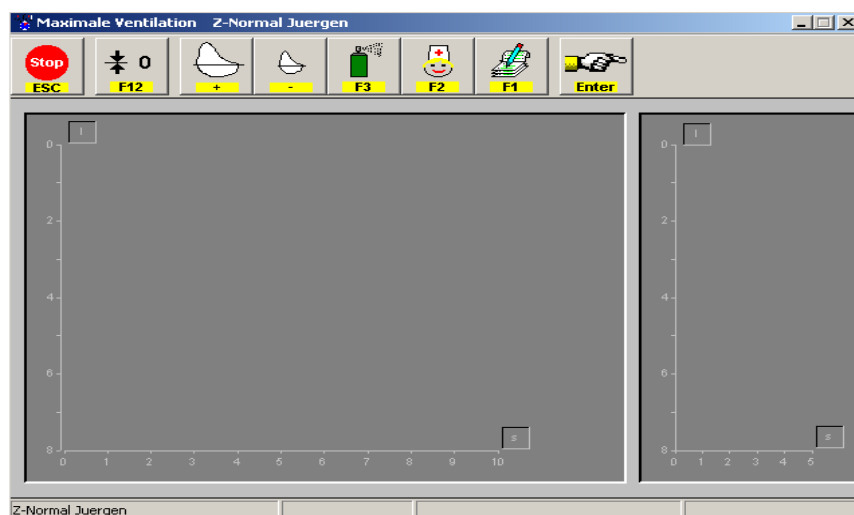
MVV may be useful in those conditions where ventilatory capacity may be impaired by mechanisms that are different to those affecting FEV₁. It can also be used to estimate maximum ventilation in cardio-pulmonary exercise testing.

MVV is measured by getting the patient to breathe in and out as rapidly and as deeply as possible for a specified time. It is similar to heavy panting. To obtain accurate results, only begin recording the measurement once the desired breathing pattern has been achieved.

4.4.1 How to perform the MVV Measurement



Selecting the icon  in the MEASURE mode enables the measurement of MVV and will lead you to the measurement window



Symbol Definitions



Stop measurement and exit the programme



Select medication



Find Zero



Define User



Zoom in



Add Remarks



Zoom out



Start Measurement

4.4.2 Performing a MVV Measurement



Select this icon or press the [Enter] key to start the measurement.

On the screen the recording is displayed as a yellow line. The patient should place their lips around the mouthpiece, forming a tight seal, and breathe normally.

The patient should be instructed to begin breathing as rapidly and as deeply as possible. The recommended frequency is 30/minute.



Start measurement by selecting the icon again.

Note: It is important that the patient continues to breathe maximally throughout the recording phase.

The measurement should use this kind of 'running start' to ensure optimum results.

The patient has to breathe maximally for 12 seconds.

If the patient is unable to continue for the whole 12 seconds, it is possible to stop the measurement by

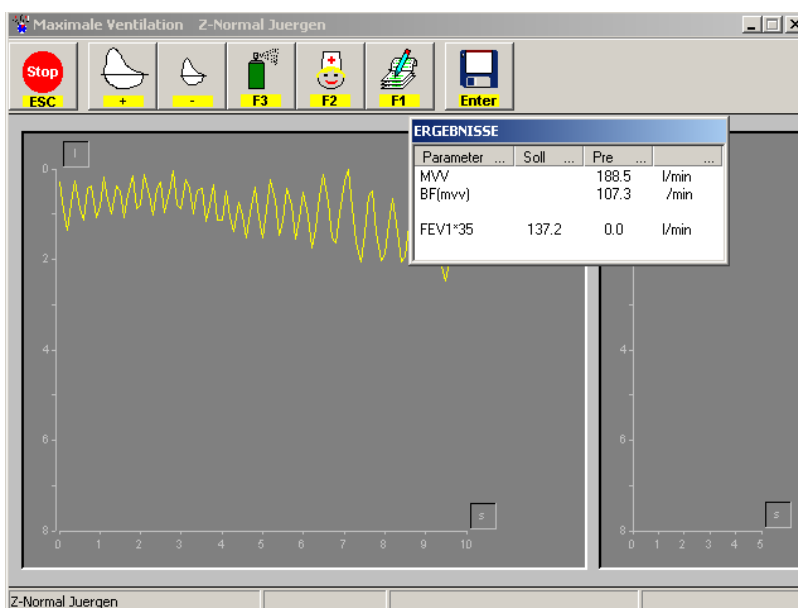


selecting this icon at any time and calculate their results from the data that has been recorded up to that point.

The maximum minute-volume will be defined by extrapolation of the volume during the real measured time. After 12 seconds the measurement will finish automatically.



Select this icon or press the [Enter] key to save the measurement and exit.



4.4.3 MVV Measurement Guidelines

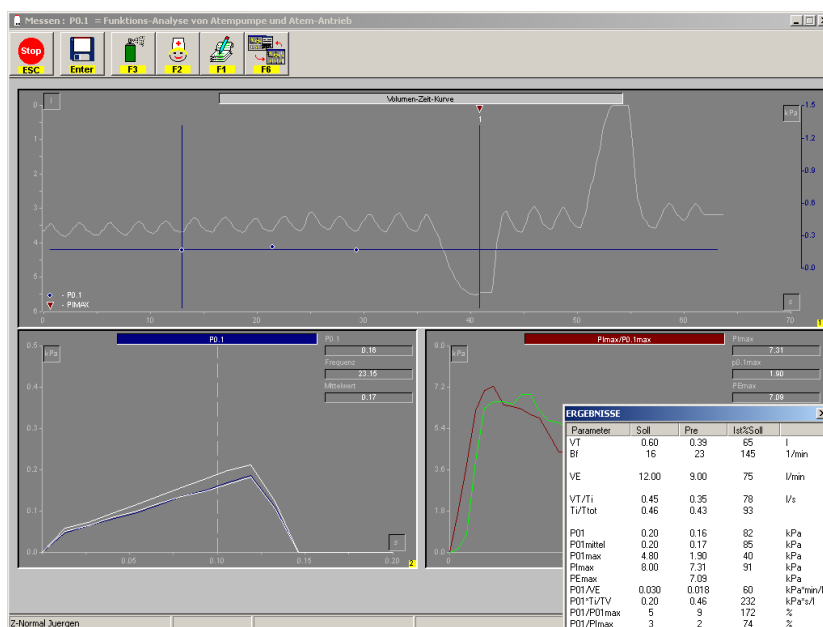
- The measurement should use "running start" to ensure best results
- In order to inhale the absolute maximum volume, the breathing frequency should not be too fast
- According to known clinical practice, the optimum is about 30 cycles per minute
- It is important that the patient uses a nose clip, forms a tight seal around the mouthpiece with his or her lips and breathes maximally throughout the recording phase

4.4.4 End Of Measurement And Evaluation



Selection of the **Enter** Icon or pressing the [Enter] key ends the measurement and displays the computed results.

4.4.5 MVV Window After Measurement

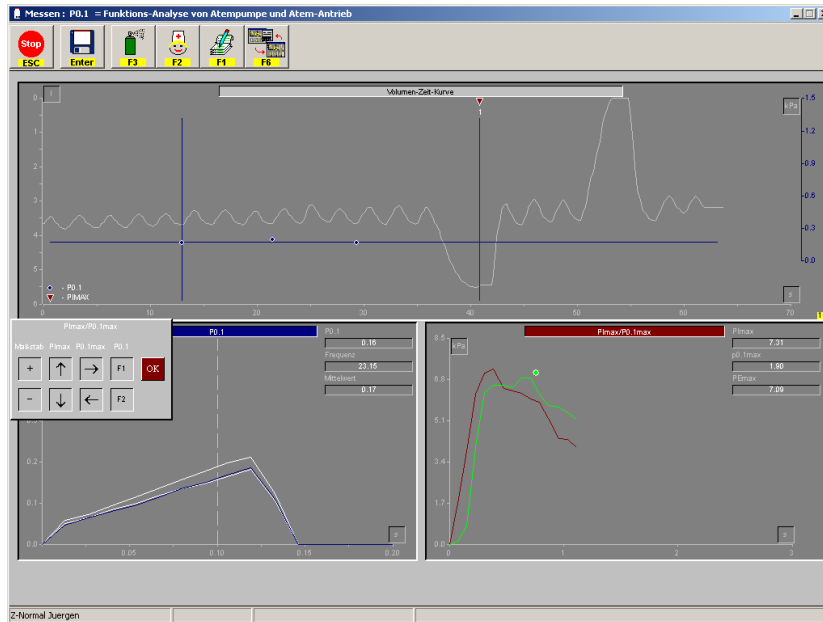


Selecting the **F6** Icon or pressing the [F6] key toggles the results window on and off.

The content of the results window can be configured by double clicking on the results window. This leads into the parameter selection window, where parameters can be selected to be displayed in the results window for future tests. The selection can be changed at any time.

4.4.6 Post Processing

A mouse click in one of the three sub windows opens a small post processing window. The post processing windows of all three sub windows are almost the same. A function is performed by clicking on the appropriate symbol.



- ▶ Click on **+** or **-** to change the scale.
- ▶ Up arrow and Down arrow icons manually change PImax value of the measurement set
- ▶ left arrow and right arrow icons selects a P0.1max value manually.
- ▶ selecting the **K** icon deactivates the selected P0.1 curve.
- ▶ Using the [F1] and [F2] keys allows manual determination of a PEmax value of the measurement.

4.4.7 Co-operation

It is hard to determine if the patient co-operates fully. It is up to the technician to carefully observe the patient and motivate him/her, to obtain accurate results.

Important: The patient must try to inhale to maximum after his/her maximum exhalation.

4.5 P0.1, P0.1max, Plmax, and PEmax

Caution: To perform this test, the shutter unit must be connected properly to the Flowhandy ZAN100 USB. Refer to chapter 1 for more information.

Note: These tests depend on good co-operation of the patient. It is important to explain every aspect of the test to the patient BEFORE the test starts and make sure the patient is willing to co-operate.

4.5.1 Definitions

P0.1	is the pressure measured at the mouth 100ms after inhalation starts during a tidal breath manoeuvre. This pressure represents the effort that the patient has to make in order to breathe normally.
P0.1max	is the pressure measured at the mouth 100ms after inhalation starts after a maximum exhalation manoeuvre.
Plmax	is the maximum pressure of inhalation which the patient can cause.
PEmax	is the maximum pressure of exhalation which the patient can cause.

P0.1max and Plmax require an identical breathing manoeuvre and will be measured simultaneously.

4.5.2 Measuring P0.1

- ▶ The patient breathes normally.
- ▶ During exhalation, click on the corresponding symbol to start the measurement.
- ▶ When the next inhalation starts, the respiratory flow will be interrupted for 120ms

The pressure is registered 100 ms after inhalation starts. The pressure represents the effort a patient can make during normal breathing

4.5.3 Measuring P0.1max

- ▶ The patient breathes normally.
- ▶ By request, the patient **exhales maximally**.
- ▶ During exhalation, click on the corresponding symbol to start the measurement.
- ▶ The patient is requested to inhale as powerfully as possible.
- ▶ When the next inhalation starts, the respiratory flow is interrupted for 1 –2 seconds.

The pressure is registered 100 ms after inhalation starts. This pressure represents the maximum effort, which the patient can make.

4.5.4 Measuring PImax

- ▶ The patient breathes normally.
- ▶ By request, the patient **exhales** maximally.
- ▶ During exhalation, click on the corresponding symbol to start the measurement.
- ▶ The patient is asked to **inhale** as deeply as possible.
- ▶ When the next inhalation starts, the respiratory flow is interrupted for 1-2 seconds.

The maximum pressure after interrupting the respiratory flow is registered.

P01max and PImax require an identical breathing manoeuvre and will be measured simultaneously.

4.5.5 Measuring PEmax

- ▶ The patient breathes normally.
- ▶ By request, the patient **inhales** maximally
- ▶ During inhalation, click on the corresponding symbol to start the measurement.
- ▶ The patient is asked to **exhale** as deeply as possible.
- ▶ When the next inhalation starts, the respiratory flow is interrupted for 1-2 seconds.

The maximum pressure after interrupting the respiratory flow is registered.

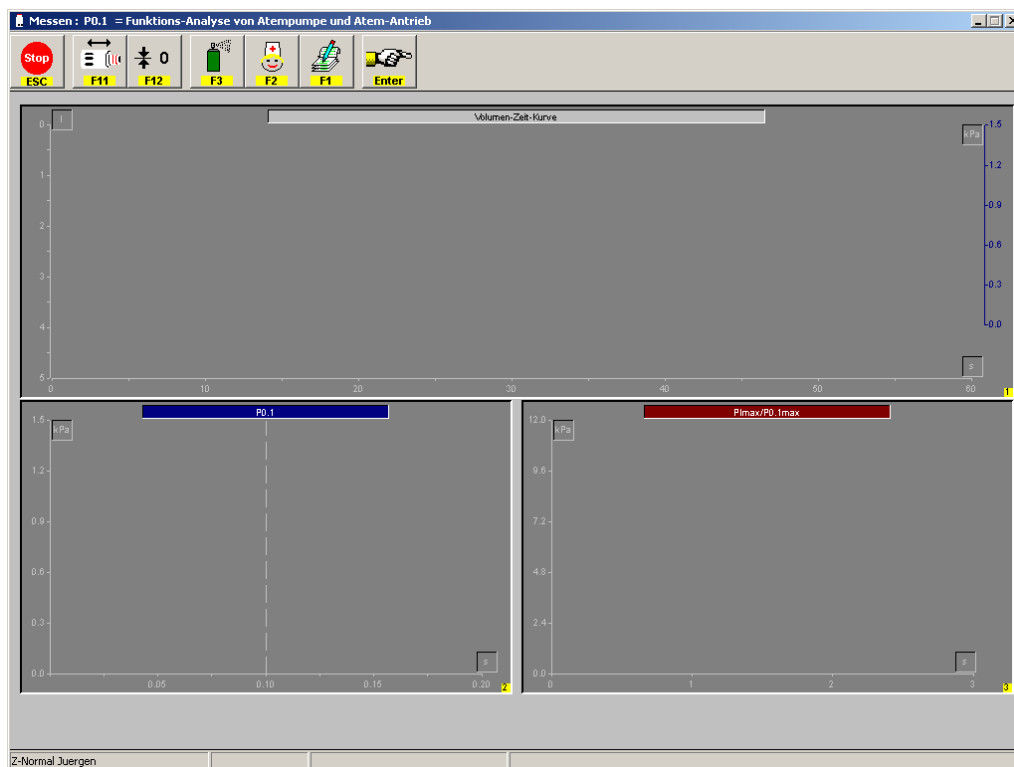
4.5.6 Performing the P0.1 Measurement



P0.1

Start measurement by selecting the P0.1 Symbols in the MEASURE menu.

Screen Before Measurement



Symbol Definitions



Stop the measurement and exit the programme



Define the user



Demonstrate the shutter



Enter comments



Reset the zero point. (Patient must not breathe through the sensor.)



Start the measurement



Select a medication.

After reset, the patient applies the nose clip and forms a tight seal with his/her lips around the mouthpiece.

Note: During resetting the zero point, the patient must NOT breathe through the sensor or his/her lips around the mouthpiece.

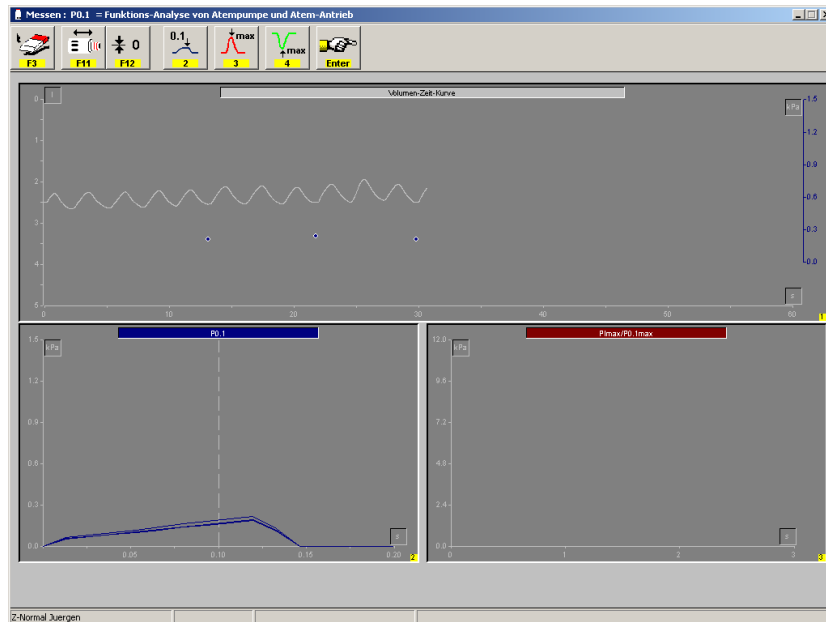


- ▶ Start the volume recording by selecting the **Enter** icon or pressing the enter key.
- ▶ The patient breathes normally.
- ▶ During tidal breath the measurement is started by randomly selecting the P0.1



Symbol

- ▶ The device will automatically interrupt the flow 120ms after the beginning of the next inhalation and records the mouth pressure



After every 2-4 tidal breaths this manoeuvre is repeated at least 5 times.

4.5.7 Performing PEmax and PImax Measurement

4.5.7.1 P0.1max and PImax

To measure P0.1max and PImax, the patient is asked to exhale as deeply as possible.



- ▶ During deep exhalation, select the PImax icon
- ▶ The device will automatically interrupt the flow after the beginning of the next inhalation for 2 sec. and records the pressure at the mouth
- ▶ The patient is asked to inhale during this time to inhale as powerfully as possible.
- ▶ Repeat this manoeuvre at least 3 times, to obtain acceptable results.

Important:

Between each PImax interruption wait for a minimum 5 tidal breaths to give the patient a rest.



4.5.7.2 PEmax

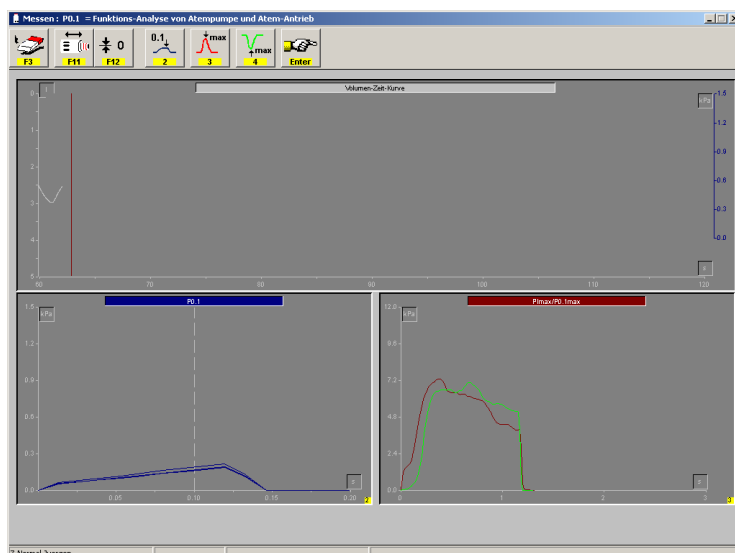
The PEmax manoeuvre is inverse to the PImax manoeuvre. The patient starts with maximum inhalation



- ▶ During deep inhalation, select the PEmax icon
- ▶ The device will automatically interrupt the flow after the beginning of the next exhalation for ca. 2 sec. and records the pressure at the mouth.
- ▶ The patient is asked to exhale as powerfully as possible.
- ▶ Repeat this manoeuvre 3 times or more.

Important:

This test should be repeated after a short pause of minimum 5 tidal breaths to give the patient a rest.



4.5.7.3 Additional recommendations

In most cases, the patient is a little nervous before the measurement and breathes too deeply or too fast. If so, the patient's tidal respiration has to be corrected by demonstrating the appropriate breathing pattern.

Important: P0.1 measurement is carried out during absolute tidal respiration.



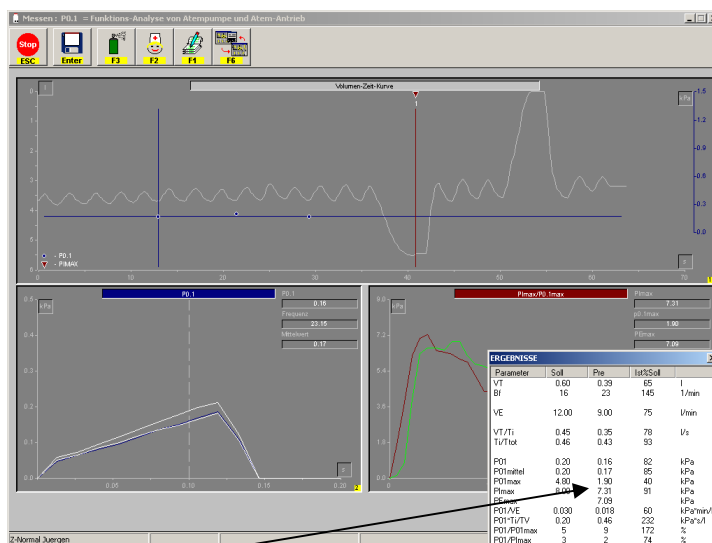
The time of interruption during P0.1 measurement is limited to 120 ms, because the patient must not change his or her breathing pattern. If possible, the interruption should be started unobserved by the patient.

Note: It is recommended to carry out the P0.1 measurement before the PImax measurement, because after maximum effort, tidal respiration will not be regular.

4.5.8 Completing the P0.1 Measurement and Analysis.



By re-selecting the **Enter** symbol, the measurement will be completed, and the results will be calculated and inserted.



With this Button you can toggle the results table on and off..

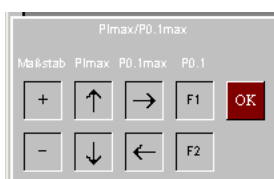
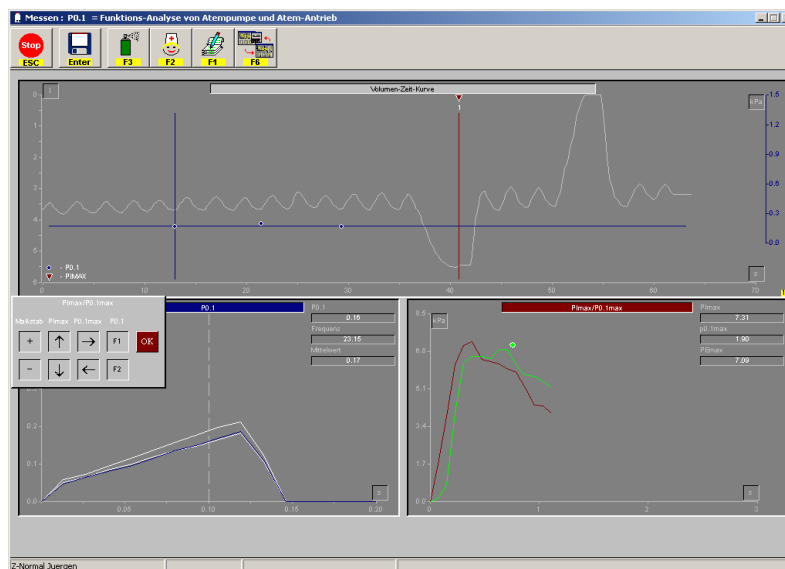
Parameter Selection

With a double click on the results window you can open the parameter selection window. Select the relevant parameters from the parameter list. They will be shown in the results window from now on.

Refer to the "parameter selection" paragraph in the "SVC Measurement" chapter for more details

4.5.9 Editing a P0.1 Measurement

By clicking on one of the three measurement screens, a small window for editing a measurement is displayed. These windows will differ a little from each other. Click on the appropriate symbol to perform the desired function.



- ▶ + Increases the scale of the graphic.
- ▶ - Decreases the scale of the graphic.
- ▶ ↑ If more than one manoeuvre has been performed, use this icon to scroll up to the previous manoeuvre.
- ▶ ↓ If more than one manoeuvre has been performed, use this icon to scroll down to the next manoeuvre.
- ▶ ← Use this icon to move left to position where the measurement should be analysed, manually overriding the computer selection.
- ▶ → Use this icon to move right to reposition where the measurement should be analysed, manually overriding the computer selection.
- ▶ K Deletes the selected P0.1 curve.

4.5.10 Co-operation

The P0.1 measurement does not require the patient to perform any controlled manoeuvres, however for P0.1max, PEmax, and PImax measurements, the patient needs to perform breathing manoeuvres for the test to be measured correctly.

Important: After deep exhalation, the patient must try to inhale with maximum effort.

To obtain valid results, the interruption should be started unobserved by the patient, so the patient does not recognise or react awaiting the interruption.

4.6 Rhinomanometry

4.6.1 Principles

Rhinomanometry measures the flow resistance of the nose.

The flow in one half of the nose is recorded and compared to the pressure which is measured in the second half of the nose.

We differentiate between the anterior and the posterior measurement.

4.6.1.1 Anterior Measurement

The anterior measurement records the pressure of both nasal tubes.

The pressure measurement is done while one side is blocked with a nasal tip or a foamed plastic.

The nasal tip or adapter is connected to the sensor by a flexible tube.

The patient breathes through the open half of the nose while the flow is measured with the sensor.

The blocking nasal tip or adapter is connected through a tube to the sensor on the rear side of the Flowhandy ZAN 100 USB. Now the patient breathes with a closed mouth through the open part of the nose while the flow is measured.

This measurement can also be performed using a mask (s.b.)

4.6.1.1.1 Using Nasal Tips

Connect the olive holder with the flow sensor on rear side of the Flowhandy.

Place two clean, disinfected nasal tips on the olive holder. Put the olives in the nostril.

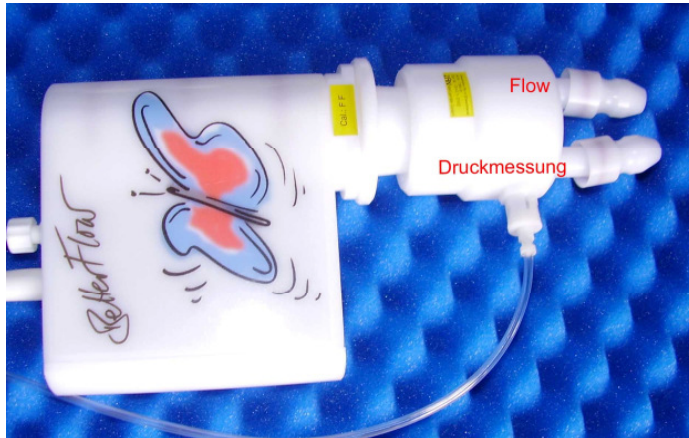


Now one of the olives is connected with a flow meter and one with a pressure meter.

The patient starts breathing through his nose.

The data of the nasal tip, connected with the flow meter will be recorded.

After the first measurement, the equipment is turned around to measure the other side of the nose.



Set-up for the use with nasal tips.

4.6.1.1.2 Using A Mask:

Even with a mask, the flow in one tube of the nose is compared to the pressure of the second tube.



Connect a new disposable nasal adapter to the internal tubing
There are different sizes available. Please choose the one which fits the best in the nostril.

Nasal adapter connected to the tubing

The mask is connected to the flow sensor and the tubing is connected to the pressure sensor on the back of the Flowhandy.



The Nasal adapter is placed in one nostril. Then the mask is placed over the patient's nose.



The patient breathes with a closed mouth. Again the flow and pressure are recorded. Placing the nasal adapter in the other nostril allows measurement of the second side of the nose.

This method is especially suited to children.

Important: Because the mask integrates nose AND mouth, it is important that the patient keeps the mouth shut and only breathes through the nose!



4.6.1.2 Posterior Measurement

Performing the posterior measurement the patient will also breathe through a mask, but the nose is not blocked. The pressure is measured in the mouth while the patient breathes through the nose.

To differentiate between the two nostrils, one can be blocked after the other to get results for each.

The patient takes the internal tubing between his lips. Use a new adapter tip for each patient. Make sure that the patient holds the tip firmly between his/her lips and the breath will only flow through his/her nose.

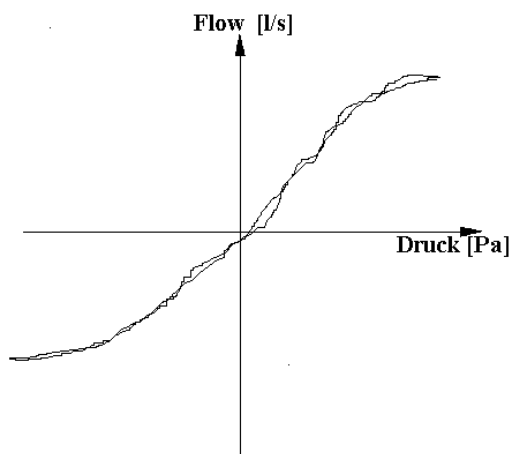
Important: After the measurement, all contaminated parts like olives, olive holder and flow sensor must be cleaned and disinfected according to the disinfection instructions. Do not reuse disposable parts like foamed plastic etc.

4.6.1.3 Important Parameters of Rhinomanometry

Short Name	Name	Meaning	measurement method
Flow 50	Flow at 50 Pa	Flow speed at 50 Pa pressure difference	Tidal breathe through one nostril
Flow 150	Flow at 150 Pa	Flow speed at 150 Pa pressure difference	Sa.
Res 50	resistance at 50 Pa	Nasal breath resistance at 50 Pa pressure difference	Sa.
Res 150	resistance at 150 Pa	Nasal breath resistance at 150 Pa pressure difference	s.a.
Res 300	resistance at 300 Pa	Nasal breath resistance at 300 Pa pressure difference	s.a.

because the flow inside of the nose is always turbulent, the pressure difference shows a square function of the flow like : $P = f(F^2)$

The result shows a curve similar to this example.

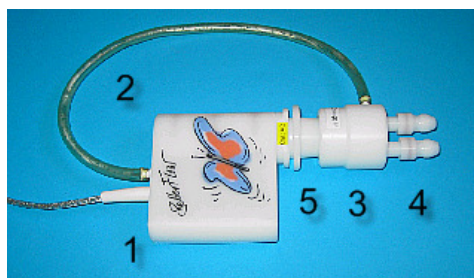
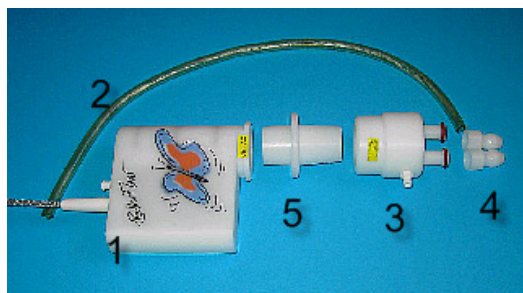


Because of the non linear relation between pressure and flow, the flow resistance is not constant and also depends on the pressure.

3 pressure values define this curve: 50 Pa, 150 Pa and 300 Pa. (s.a.)

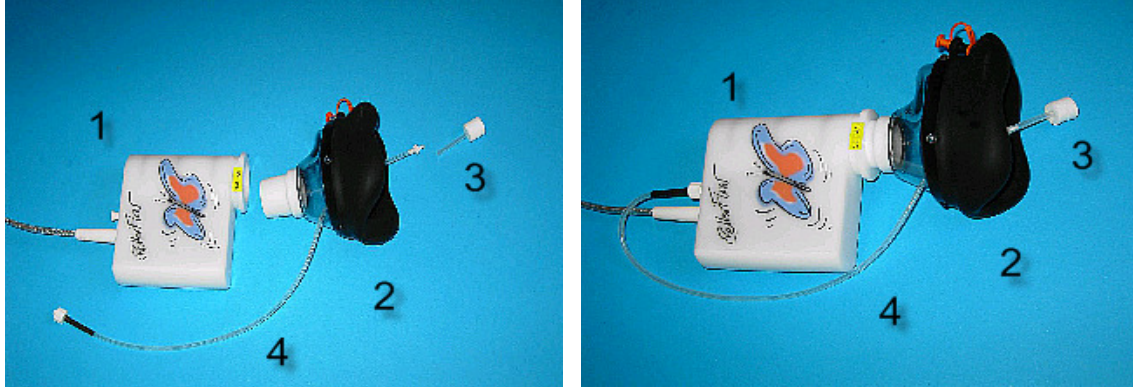
4.6.2 Assembly And Connection Of The Parts

4.6.2.1 Using Olives



1. Flowhandy ZAN 100 USB
2. Tubing (connect to Olive holder (3) and Flowhandy ZAN 100 USB (1))
3. Put Olive holder on the adapter (5) and the Flowhandy ZAN 100 USB (1)
4. Put the 2 Olives (4) on the Olive holder (3)

4.6.2.2 Using A Mask

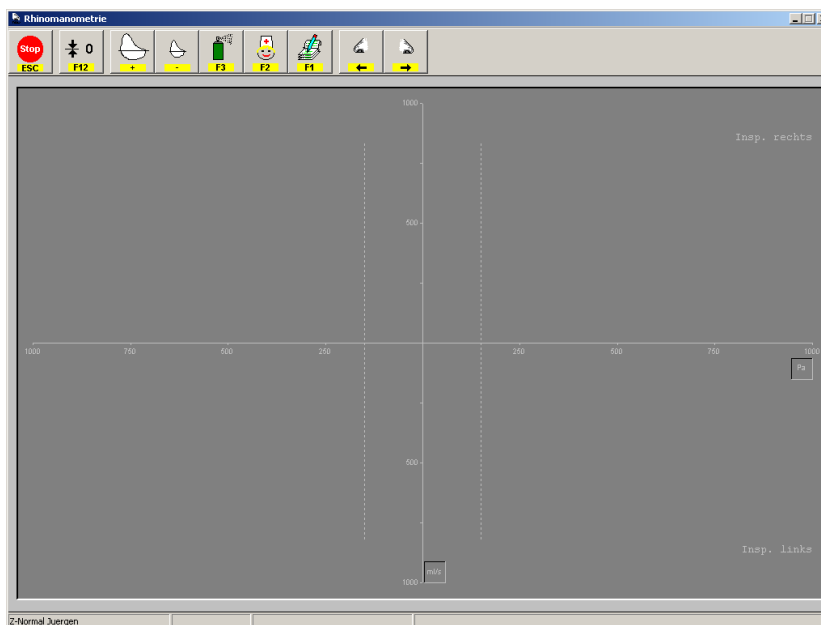


1. Flowhandy ZAN 100 USB
2. Put the Mask (2) on the Flowhandy ZAN 100 USB (1)
3. Connect the Nasal adapter (3) with the tubing to the Flowhandy ZAN 100 USB (1)
4. Connect the tubing to pressure sensor of the Flowhandy ZAN 100 USB

4.6.3 The Rhinomanometry Window before Measurement

Start the measurement by either selecting  **Rhino Olive** or  **Rhino Maske** according to your equipment.

You will then see this window



Symbol Definitions



Cancel measurement



Select medication



reset zero (patient must not breathe through the sensors)



Define user



Zoom in



Enter remarks



Zoom out



Start measuring the left part of the nose



Start measuring the right part of the nose

4.6.4 Performing Rhinomanometry

Note : Before starting the test, the patient should clean his nose properly in order to obtain reproducible results

Usually rhinomanometry does not require special co-operation from the patient. Sometimes the depth of the breath has to be adapted.

- Click on  or  will start measurement of the right or left nose.

You will see this hint
Please insert pressure olive into the right nostril



When measuring the left part of the nose, the pressure olive (or the foamed plastic of the nasal adapter) has to be positioned in the right nostril. The pressure olive is the one which is connected to the part of the olive holder where the tubing is connected.

To measure the right side of the nose, place the pressure olive into the left nostril.

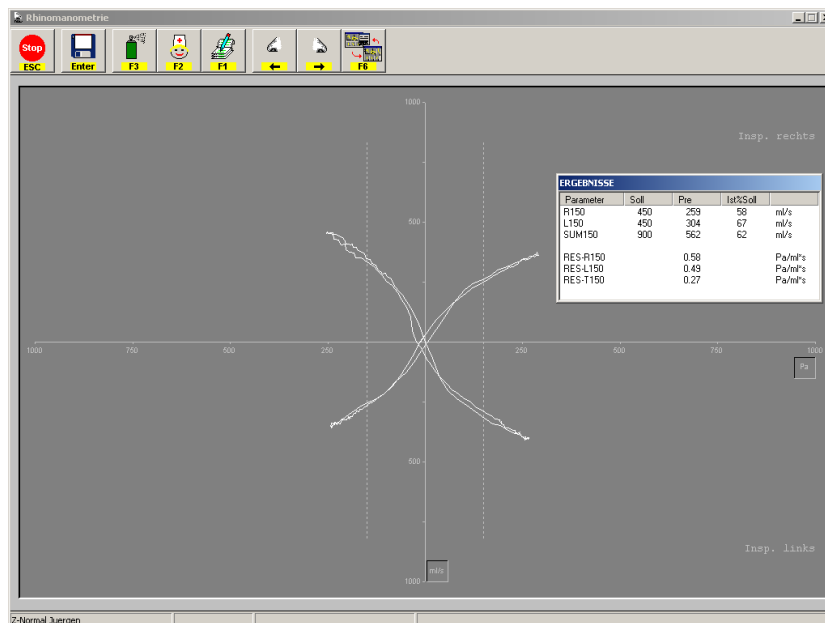
- The patient starts breathing through his/her nose.



It is advisable to delete the first breaths from the display selecting the  icon or by pressing the F3 key, when the curves show wide variation.

- Selecting the  icon or pressing the Enter key after 5 breaths, stops the measurement and displays the results.
- Re-selecting one of the icons   repeats the test, or initiates measurement of the other part of the nose.
- Selecting this icon  or pressing the Enter key when the result window is up, saves the results and ends the test.

4.6.5 The Rhinomanometry Window After Measurement



Symbol Definitions



Toggle result window on and off



Save data

Parameter Selection

With a double click on the result window you can open the parameter selection window. Select the relevant parameters from the parameter list. They will be shown in the result window from now on.

4.6.6 Special Recommendations

When using the mask, make sure that the mask is tightly connected to the patients face.

When using olives, make sure that they are pressed from below into the nostrils, and form a tight seal. They should not deform the nostrils. Different sizes of olives are available so find matching pairs.

Two vertical lines mark the 150 Pa pressure on the screen.

The patient should breathe in a relaxed manner, but the dotted lines need to be reached or passed.

If the S curves do not reach these marks, the patient has to be asked to breathe deeper.

4.7 Sniff

4.7.1 Basics

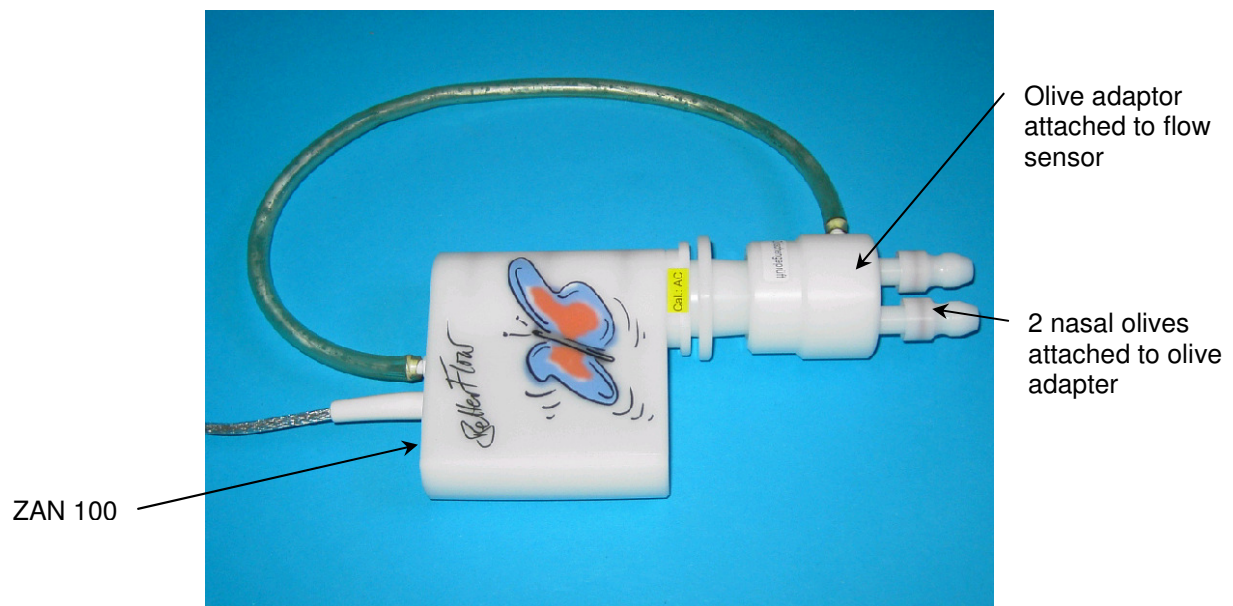
The Sniff measurement is a good measure of global respiratory muscle strength. It is the peak pressure obtained during a short, sharp voluntary inspiratory manoeuvre, performed through one or both unoccluded nostrils. The mouth must be closed during the manoeuvre.

During a maximal sniff manoeuvre, the unobstructed nostril will collapse. The pressure in this nostril reflects the pressure in the nasopharynx which is a good indication of alveolar pressure, which in turn approximates oesophageal pressure and therefore inspiratory muscle strength.

The manoeuvre should be repeated many times: there is a learning process associated with the technique.

4.7.2 Assembly and connection of the Sniff device

The nasal olives are connected to the flow sensor via the olive adaptor. A pressure tube links the adaptor to the pressure sensor inside the flow handy, as shown.



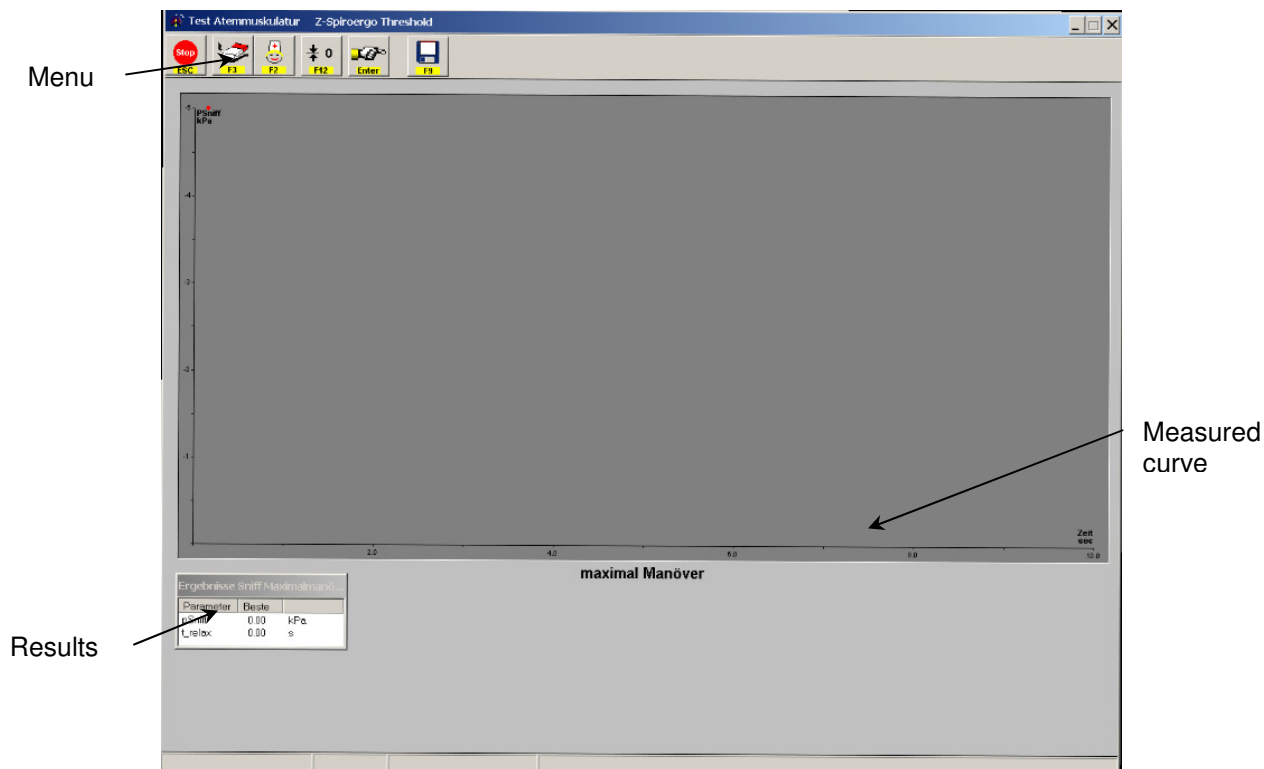
The two nasal tips should be pressed upwards against each nostril from below. Be sure there's a good seal between the olives and the nostrils.



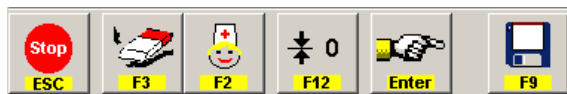
One of the two olives is connected to the flow sensor, the other one to the pressure transducer. The pressure in the unobstructed nostril is measured.

4.7.3 The window prior to the measurement

After starting the program, the following window opens:



Meaning of the icons



End test



Set the zero



Delete previous curve



Start next measurement



Enter examiner's name



Save results

4.7.4 Performing the Sniff measurement

Ask you patient to blow their nose prior to beginning the effort. The nostril should be unobstructed.

The measurement is started by pressing the [Enter] key or by clicking on this icon  .

Caution: The patient should press the nasal olives firmly to his/her nostrils and then sniff as forcefully as possible.

Important: The mouth must remain closed so no pressure is lost through the mouth.
The pressure curve appears in red on the screen. The measurement ends automatically after 10 seconds or with the next expiration.

Important: If the patent starts to exhale, the measurement will be stopped immediately.

The measurement may be repeated as often as required by starting it again with the Enter key  . All the measurements will be saved, the best one then can be selected during the analysis.

Once sufficient manoeuvres have been carried out, the F9 save key  can be clicked to save and end the measurement.

The maximum Sniff pressure will be measured for each curve.

The program shows the last pressure curve on the screen automatically.

4.7.5 Analysis of the measurements

- To select the best manoeuvre, click twice on the icon  with the mouse.
- Activate the right window by clicking on it.
- By pressing the Space key or the  icon, the pressure curve can be selected manually.
- When finished, press Esc or click on the  icon.
- Select Yes to save your changes and No to exit without saving.
- To print measurements, select the icon  .

4.7.6 For acceptable results:

- The olives must be pressed upwards against the nostrils from below, forming a tight seal. Do not deform or contort the nostril. The measurement is extremely difficult if there is airway distortion or if the nose is completely blocked.
- The patient must keep their mouth closed during the measurement.
- The sniff must be maximal. Repeating the measurement is strongly recommended.

4.8 Compliance Measurement

The compliance measurement examines the elasticity of the lung tissue

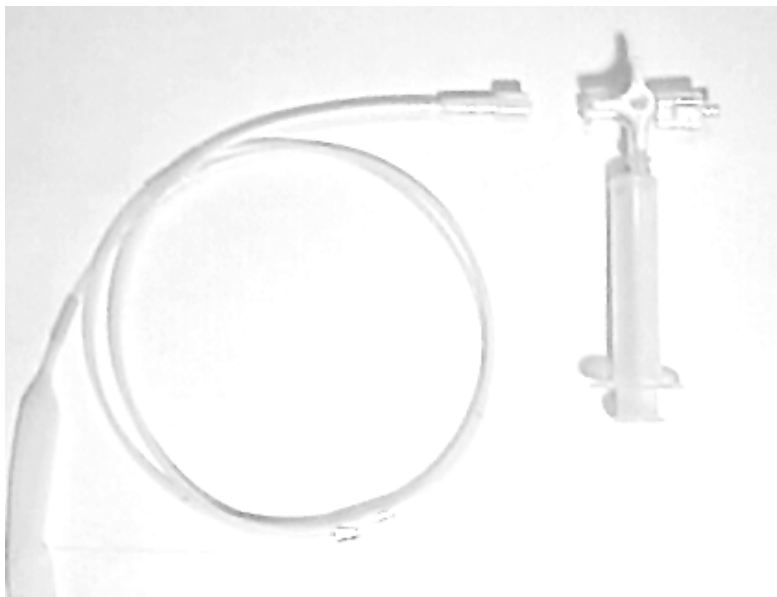
A balloon catheter is positioned inside the patients oesophagus to measure the oesophageal pressure. Simultaneously an additional sensor measures the volume.

The compliance curves are diagrams of volume in relation to the oesophageal pressure.

4.8.1 Application Of The Catheter

Placing the catheter in the right position is the most difficult part of the procedure

- ▶ Turn the switch of the 3 way T-valve so that the syringe is directly connected to the catheter as shown in the picture below.



- ▶ Moisten the balloon catheter and cover with lubricant.
- ▶ Empty the tip of the balloon catheter
- ▶ Carefully move the catheter through the nose into the gullet.
- ▶ It is recommended that the patient swallows steadily or drinks some water or tea.
- ▶ The balloon is approximately in position, when the small dotmark on the catheter tubing has reached the nostril

Caution: Select the programme module 'Compliance measurement' **BEFORE** the catheter is connected to the sensor.



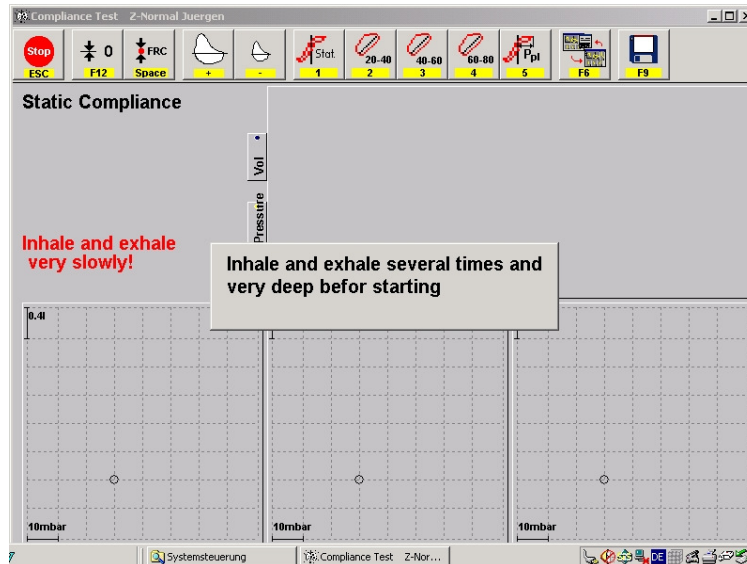
Zero points on all sensors are reset during the start of the programme and the patient must not breathe at this time through any of the sensors.

4.8.2 Programme start

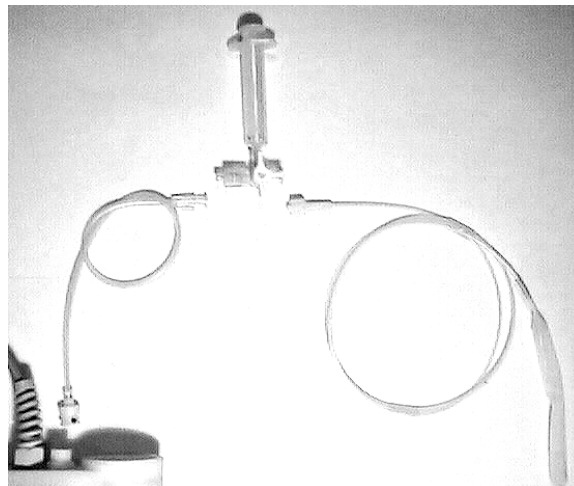


Select the Symbol from the MEASURE mode menu.

The following screen will show up.



Now connect the catheter to the sensor. (Note: the balloon catheter has been in place at this time but not yet connected to the sensor)



Connect the balloon to the syringe using the three way valve and inflate 3-5 ml air to unfold the balloon. Then switch the valve so that the balloon is connected to the sensor.

On screen, the oesophageal pressure signal can be observed in the right most sub window to fine tune the position of the catheter.

The catheter is in the right position, when after inhaling the curve goes down. When the curve goes up on inhalation, the catheter is obviously placed in the stomach and needs to be drawn back.

To avoid sliding of the catheter, use adhesive tape and fix the catheter tubing at the nose.

4.8.3 Three Types Of Measurement

4.8.3.1 Static Compliance

From tidal breathing, the patient inhales deeply three times and then exhales as deeply as possible. Then he/she returns to normal tidal breathing.

It is important that the patient performs the inhalation and exhalation as slowly as possible to emulate quasi static behaviour.

The compliance value is computed from the gradient in the middle, linear part of the curve

4.8.3.2 Dynamic Compliance

The patient breathes with normal or slightly accelerated speed and with normal depth (appr. 0.5l/breath)

The compliance is computed from the gradient at the inversion point between inspiration and expiration.

4.8.3.3 Frequency Dependant Compliance

The patient breathes with normal breath depth but with accelerated speed.

The compliance is computed from the gradient at the inversion point between inspiration and expiration.

4.8.4 Performing the Compliance Measurement

Click on one of the three sub windows to start recording.

The current data input is displayed in the upper right sub window.

After a complete tidal respiration selecting the  icon or pressing the F5 key saves the dynamic compliance curve in the intermediate buffer.

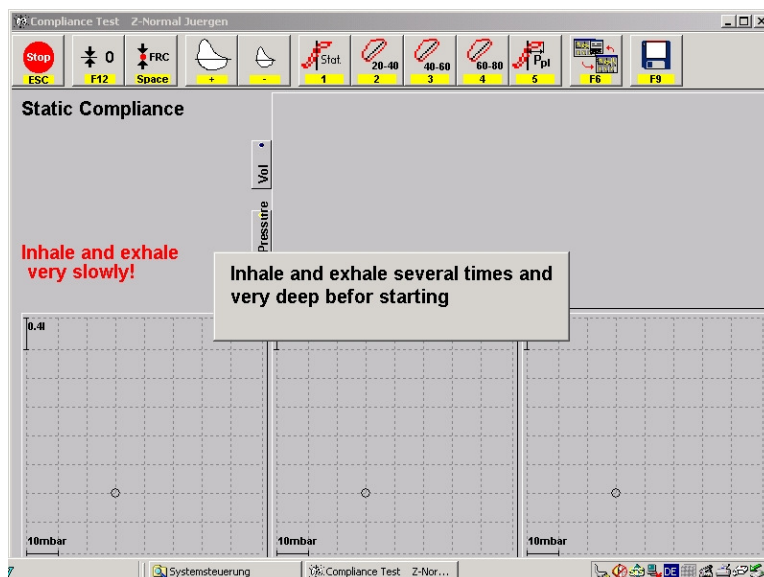
The static compliance curve is saved by selecting the  or pressing the F4 key. Selecting the  (F6 key) saves the frequency dependant compliance in the intermediate storage.

You can see the curves in a raster field in the middle row of the right half of the window and they are kept until the final results are computed. In the upper right corner of this raster field, you can find the breathing frequency at which the data has been recorded.

Up to 10 different curves of each kind can be placed in this intermediate storage.

Use F3 or select the  icon, to delete unacceptable measurements or tests with too many artefacts.

In order to Stop recording, select the  icon or press [enter]

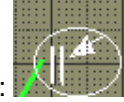


Change the curves scale, using  buttons (or plus or minus keys)

To activate a particular compliance curve, click on the corresponding raster field. This will copy the curve into the left part of the screen. The raster field shows a different background colour when selected.

Because the compliance is computed from the gradient of the curve, the result is displayed as a green straight line overlay in the curve display. The gradient of this straight line displays the result of the computations.

To manually modify this value, pick one end of this line with the mouse cursor. You know that you have



found the right point, when the mouse cursor changes to this layout :

Press the left mouse button and move the line into the desired position.



Select **F3** or press the F3 key to remove the selected curve from the set. It means the curve is still in the file, but ignored for printing.



All displayed data and curves are stored when the [enter] key is pressed or the **Enter** icon is selected.

4.9 Bodyplethysmography

4.9.1 Basic Information

4.9.1.1 Intention of the Bodyplethysmography

Whole-bodyplethysmography is known as the gold standard in lung function diagnostics. It is able to measure the resistance of the airways as well as static lung volumes. Airways resistance is an effort-independent measure, requiring only quiet breathing. The measurement of the TGV is combined with simple spirometry to provide the total lung capacity and all its subdivisions.

4.9.1.2 Resistance

Airways resistance is a very sensitive parameter. It is often used to assess central airways obstruction in patients unable to perform a forced manoeuvre. A decrease in airways resistance after a bronchodilator is a strong indicator for a reversible and drug sensitive obstruction.

4.9.1.3 Thoracic Gas Volume TGV

The second important parameter measured with the bodyplethysmograph is the thoracic gas volume.

The TGV is the volume of ventilated and non-ventilated gas in the thorax at the time a shutter interrupts airflow at the mouth. On the ZAN500/530, the TGV is measured at the end of a tidal breath, ie at FRC. FRC is the point at which the elastic recoil of the lung and the recoil of the chest wall are equal and opposite and it is important for the correct calculation of TLC and airway resistance.

Measuring the lung volume at the same time as airway resistance allows the calculation of the specific conductance of the airways, sGaw.

4.9.1.4 Measurement Principles

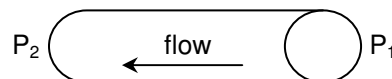
Neither resistance nor TGV can be measured directly, so indirect methods are employed to determine these parameters.

4.9.1.4.1 Resistance

Resistance to airflow is defined as the quotient of pressure and flow.

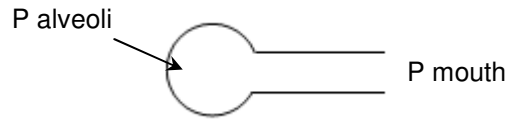
$$Resistance = \frac{PressureChange}{flow}$$

To determine the resistance to airflow of a pipe, the pressure at either end of the pipe, P₁ and P₂, and the actual flow must be recorded.



$$Resistance = \frac{P_2 - P_1}{flow}$$

The airways of the lung are a widely branched system of pipes running between the alveoli and the mouth.



To measure airways resistance it's necessary to measure the alveolar pressure changes, P_{alv} , and the mouth pressure changes, P_{mouth} , during breathing.

$$R_{aw} = \frac{P_{alv} - P_{mouth}}{flow}$$

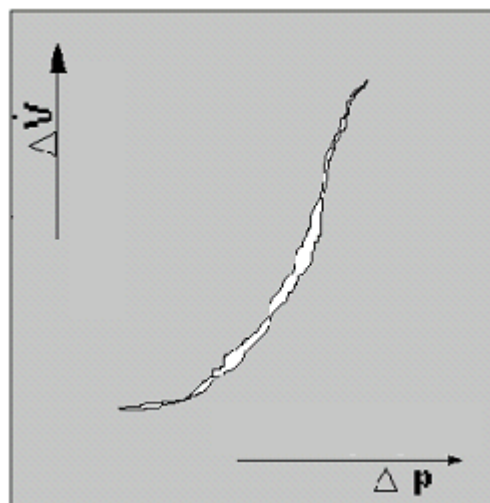
Firstly, with the shutter open, flow and pressure at the mouth are recorded.

To measure the alveolar pressure during breathing a body plethysmograph must be used.

While the subject is seated within an airtight chamber, a shutter is used to stop airflow at the mouth. With no airflow, the alveolar pressure is proportional to chamber pressure and so the alveolar pressure can be calculated.

Airway resistance can be calculated by combining the measurements from the open shutter and closed shutter recordings.

Resistance Loops



Because the resistance is not constant, but changes with the flow rate, the resistance can curve show a sigmoid shaped loop.

4.9.1.4.2 TGV

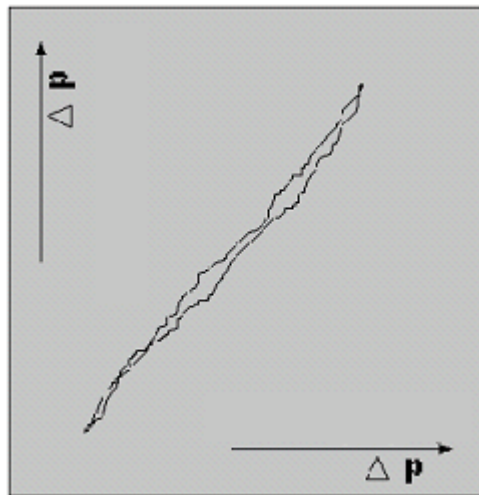
TGV is based on Boyle's law.

To measure TGV a shutter is closed at the end of a normal breath and the subject breathes lightly against the shutter. Simultaneously the pressure differences in the patient's mouth and inside of the chamber are measured.

The lung volume at the time of occlusion can be calculated using these pressure differences, the known volume of the box and calibration factors.

$$\text{TGV} = K \times (\Delta P_{\text{MOUTH}} / \Delta P_{\text{CHAMBER}})$$

TGV Graph



There should be a linear relationship between mouth pressure and chamber pressure.

4.9.2 Performing the Measurement

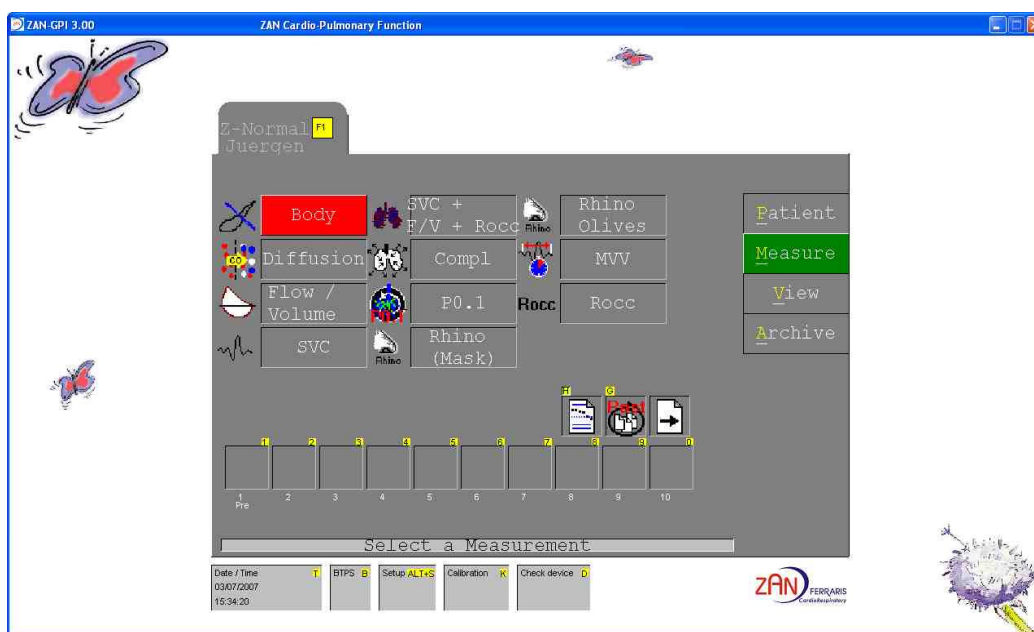
4.9.2.1 Starting the Measurement Programme

After a patient has been recalled or created in the main screen, change to the Measure mode. The screen will now show all installed measurement procedures, according to the licence code.

On the 'Measure' screen select the

Body

button with two consecutive clicks to display Bodyplethysmography main test screen.



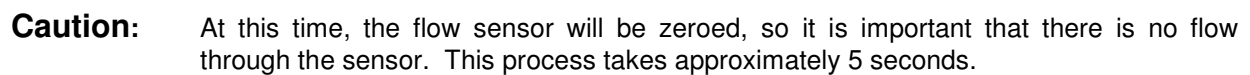
Body

Note: After the first click on the button, the button colour turns to red to show that it is pre-selected. The next click on this button will start the measurement programme. This is not a 'double click' but two consecutive clicks.

4.9.2.2 The Multi Measurement Screen

The main screen is the centre of the Bodyplethysmography measurement programme. Firstly, it displays the results of all performed examinations as a synopsis and secondly it works like a big graphical menu, from where the user can branch into the several sections.

In a way, one may look at the main screen as a container combining all the different and basically independent methods to one complex process.



The main screen is divided in a iconified menu and 5 sections.

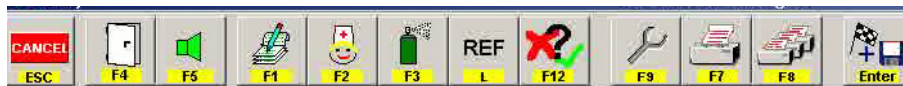


Right below, the subwindows for SVC, F/V, Resistance and TGV measurements are located. Although these four sections may look very similar, they have their own special structure as one can see by the structure of the axis and submenus in the particular section.

Results are displayed in the lower half of the screen.

4.9.2.2.2 Symbols of the Main Menu

Global functionalities can be invoked from this line of buttons, the main menu:



A simple click on the icon activates the corresponding function. If one lets the mouse pointer hover over the icon for a couple of seconds a hint is displayed, giving a brief description of the icon's function.

Symbol definitions



Select this icon or press the [ESC] key to stop the measurement and exit the program.



Select this icon or press the [L] key to select a reference value from another test for comparison.



Select this icon or press the [F4] key to open the door.



Select this icon or press the [F12] key to check that results meet ERS/ATS 2005 standards.



Select this icon or press the [F5] key to switch the speaker on or off.



Select this icon or press the [F9] key to enter the test setup.



Select this icon or press the [F1] key to display a dialog box to enter comments.



Select this icon or press the [F7] key to print the current screen.



Select this icon or press the [F2] key to define the user.



Select this icon or press the [F8] key to print out one or more templates.



Select this icon or press the [F3] key to select the medication.



Select this icon or press the [Enter] key to save the measurement and exit.

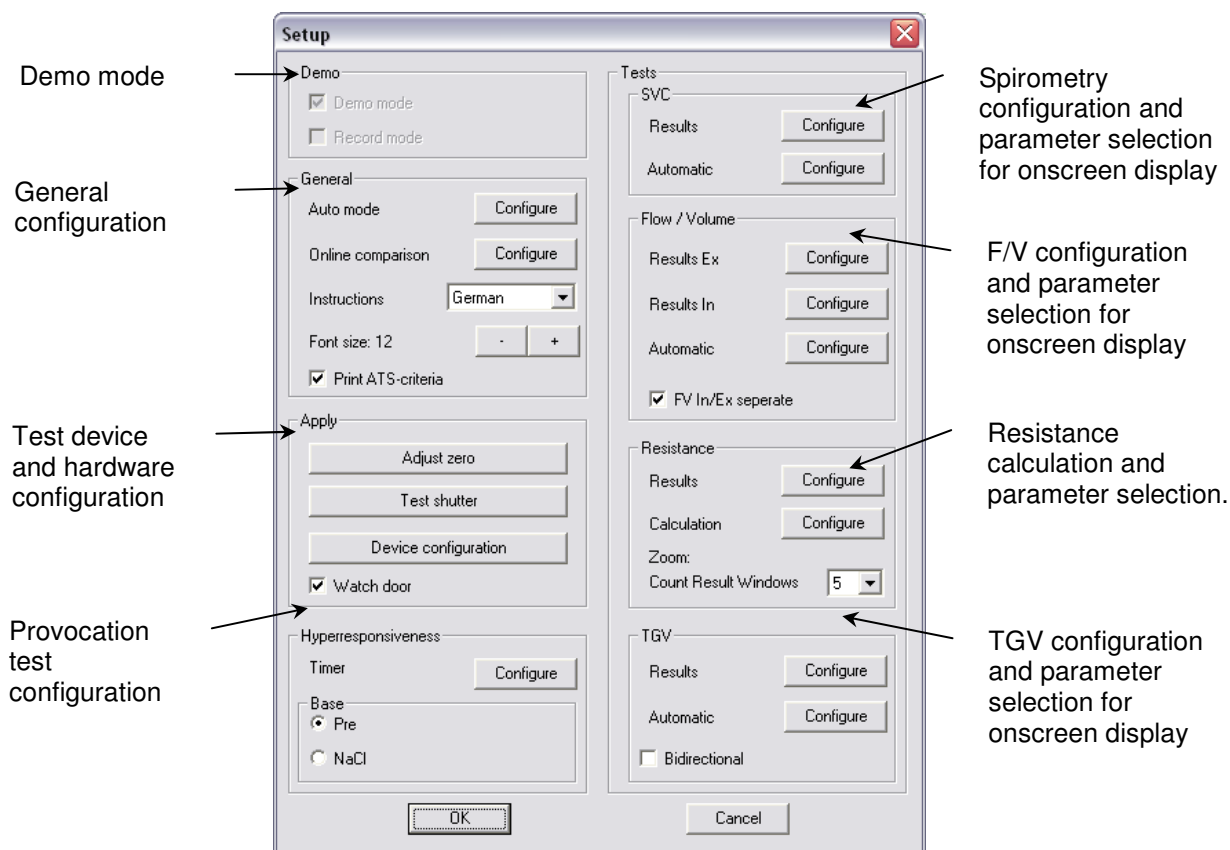
Many symbols have already been explained in the SVC chapter. Please look for additional information in Chapter 4.

4.9.2.2.3 The Setup



The body software provides a special integrated setup window, where all measurement procedures can be configured.

Selecting the  icon or pressing the [F9] key opens the set up window.



Bidirectional: with this box checked the shutter will close for a preset period (usually 3 or 5 sec). The subject lightly pants until the shutter opens before inspiring to TLC. If the box is left unchecked, only one effort against the shutter is required. (See Chapter 5.1.2.5.2 for measurement technique.)

4.9.2.2.4 Subwindows

The upper half of the screen is occupied by the four test subwindows.

Every subwindow has its own small icon-menu, from where particular functions can be executed. The following icons can be found in each of them:



Click the go icon to start the test



To make the measurement full screen



To increase the scaling of a graphic



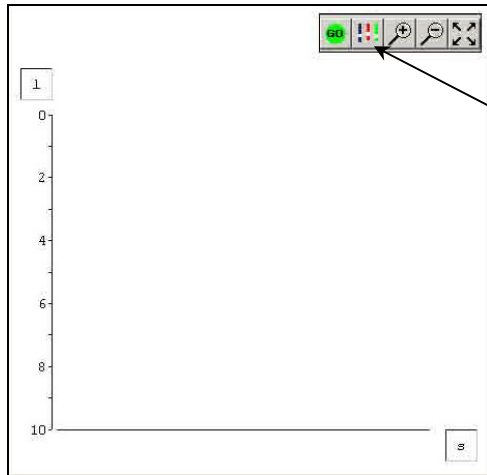
To return from measurement full screen to multi measurement screen



To decrease the scaling of a graphic

Additional buttons can be found depending on the particular test window.

4.9.2.2.4.1 SVC

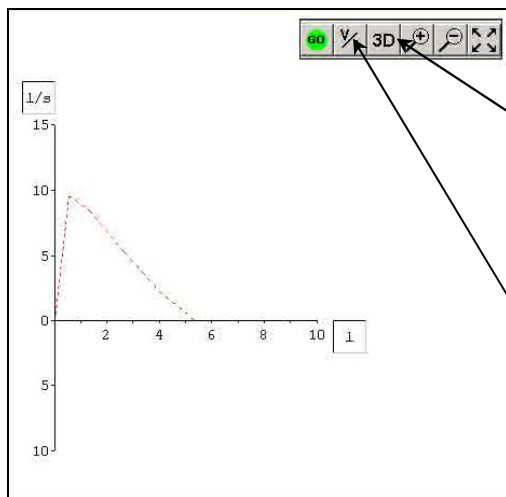


To switch SVC from bar graph to volume-time graph



To switch SVC from volume-time graph to bar graph

4.9.2.2.4.2 Flow/Volume



Switch to 3D view



Switch to 2D view

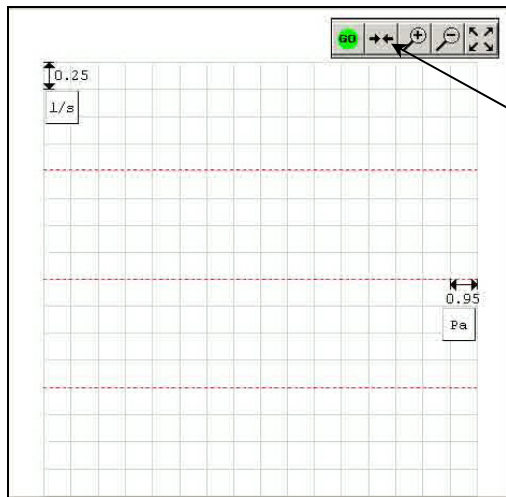


To show F/V loops



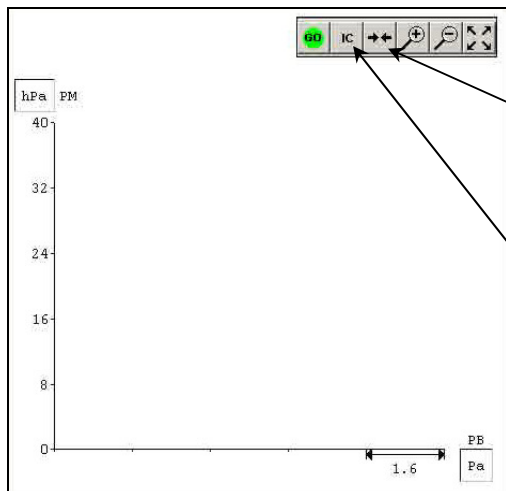
To show volume-time graph

4.9.2.2.4.3 Resistance



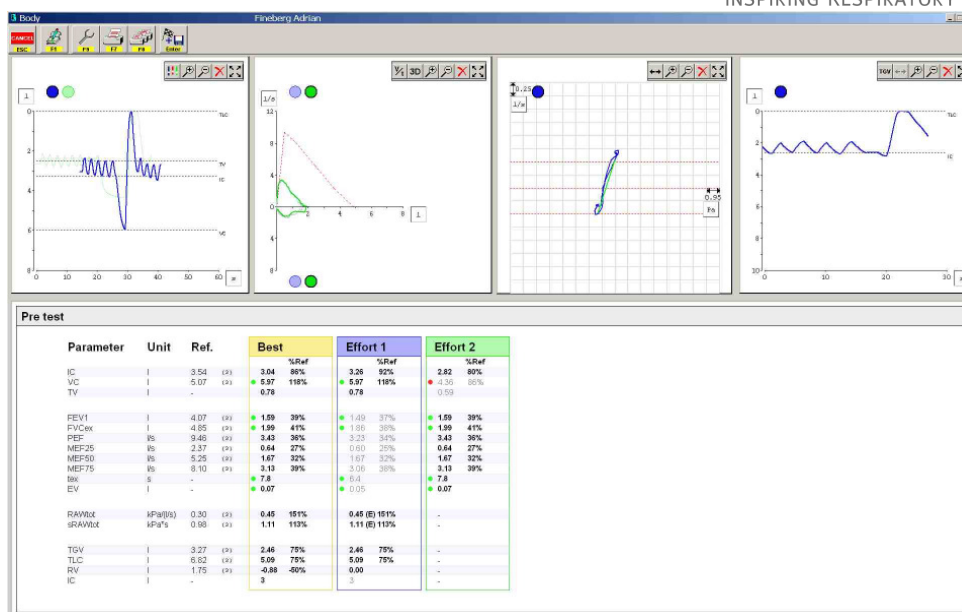
-  To show resistance loops overlapping
-  To show resistance separately

4.9.2.2.4.4 TGV



-  To show TGV manoeuvres overlapping
-  To show TGV manoeuvres separately
-  To show the IC manoeuvres of the TGV efforts
-  To show TGV manoeuvres

4.9.2.2.5 The Results Window



Bodyplethysmography is a diagnostic procedure, which is combined from a series of components:

- A measurement consists of 4 examinations, spirometry, Flow/Volume, resistance and TGV. Each examination has a unique color code to determine what particular examinations are combined to one measurement.
- 3-9 measurements built one test (pre- or post medication for example)
- All tests are sampled in one slot (see below)

The cover sheet of a slot is the BEST curve.

One bodyplethysmography test may consist of several slots.

4.9.2.2.5.1 The Effort/Best View

Pre test					
Parameter	Unit	Ref.	Best	Effort 1	Effort 2
IC	l	3.54 (x)	3.04 86%	3.26 92%	2.82 80%
VC	l	5.07 (x)	5.97 118%	5.97 118%	4.39 86%
TV	l	-	6.78	6.78	6.59
FEV1	l	4.07 (x)	1.59 39%	1.49 37%	1.59 39%
FVCex	l	4.85 (x)	1.99 41%	1.88 39%	1.99 41%
PEF	l/s	9.46 (x)	2.43 26%	2.23 24%	2.43 26%
MEF25	l/s	2.37 (x)	0.64 27%	0.60 25%	0.64 27%
MEF50	l/s	5.25 (x)	1.67 32%	1.67 32%	1.67 32%
MEF75	l/s	8.10 (x)	3.13 39%	3.06 38%	3.13 39%
Isx	s	-	7.8	6.4	7.8
EV	l	-	6.07	6.05	6.07
RAWtot	kPa(l/s)	0.30 (x)	0.45 151%	0.45 (B) 151%	-
sRAWtot	kPa/s	0.98 (x)	1.11 113%	1.11 (B) 113%	-
TGV	l	3.27 (x)	2.46 75%	2.46 75%	-
TLC	l	6.82 (x)	5.69 79%	5.69 79%	-
RV	l	1.75 (x)	-0.88 -50%	0.00	-
IC	l	-	3	3	-

The Effort/Best View displays a particular test. Every test is displayed in a coloured column with two columns of numbers: Value and % of the expected value.

In the leftmost columns the descriptions of the lines are printed like: parameter name, unit, expected - and normal value of the parameter

Coloured dots at beginning of a line in a particular column depict if the value is valid according to the ATS/EU criteria.

4.9.2.2.5.2 The 'BEST' Column

The best column displays a compilation of the results from all included efforts, according to ERS/ATS guidelines, ie the highest FEV₁ and FVC are displayed in the best column while the remaining forced spirometry parameters are from the selected loop. Other parameters may be averaged, like TGV, while some may be calculated using the best or averaged values.

	Best	Effort
(3)	3.64	3.26
(3)	5.97	5.97
(3)	9.78	9.78
(3)	1.59	1.49
(3)	1.99	1.56
(3)	3.43	3.23
(3)	9.54	9.60
(3)	1.67	1.67
(3)	3.13	3.06
(3)	7.8	6.4
(3)	9.67	9.05
(3)	0.45	0.45
(3)	1.11	1.11
(3)	2.46	2.46
(3)	5.09	5.09
(3)	-0.88	0.00
(3)	3	3

4.9.2.2.5.3 The Slot View

Parameter	Unit	Ref.	Pre test	Post
VC	l	6.82 (3)	5.97 87%	7.14 100% +19.6%
IC	l	5.07 (3)	3.28 65%	4.22 83% +28.6%
ERV	l	1.86 (3)	2.69 144%	2.92 157% +8.7%
IRV	l	-	2.50	3.51 +40.2%
TV	l	-	9.78	9.71 -0.6%

The slot view display an overview over all performed tests. The frontpage of each slot is taken from the BEST view of the Effort/Best view

Double clicking on the result window toggles between the two display modes.

4.9.2.3 Measurement of SVC and Flow/Volume



Selecting the  Button in the corresponding subwindow starts the examination. The corresponding measurement window will be displayed as it is explained in Chapters 4.1 and 4.2.

4.9.2.4 Airways Resistance Measurement

The patient enters the chamber and the door is closed. The door has to be pressed tightly against the door frame and the magnets have to lock in with a click sound.

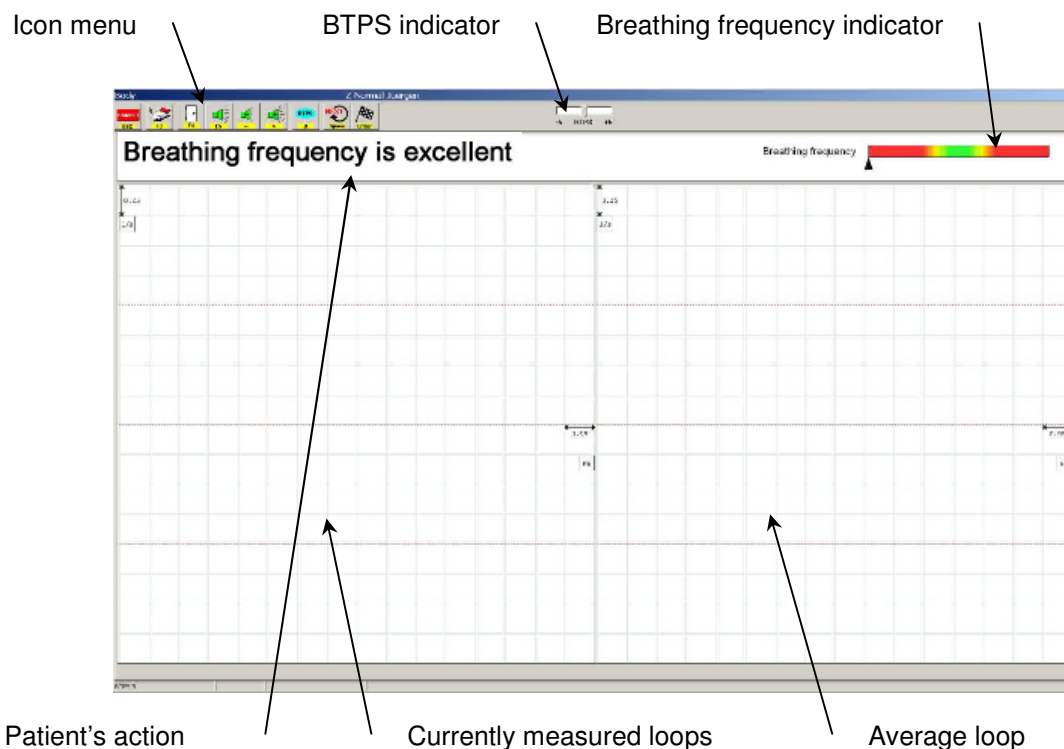
Caution : It is important to lock both magnets of the door. The light on the door panel will illuminate when both magnets are locked.



4.9.2.4.1 The Measurement Screen

Selecting the  Button in the resistance subwindow starts the resistance measurement. The system switches from the overview to the measurement screen.

4.9.2.4.1.1 Components of the Measurement Screen



4.9.2.4.1.2 Symbols of the Icon-Menu

The resistance measurement window has its own icon menu to call particular functions during the test.



A single click on the icon triggers the function. If the mouse pointer hovers over the icon for a while, a description of the icon's function is displayed.

Symbol Definition



Select this icon or press the [ESC] key to end the test without saving.



Select this icon or press the [Enter] key to save the measurement and exit.



If the trace is unsatisfactory, the measurement can be re-started by pressing the [F3] key. This deletes the results and continues the measurement.



Select this icon or press the [space] key to save the measurement and start a new measurement.



Select this icon or press the [F4] key to open the door.



Select this icon or press the [B] key to adjust the BTPS auto-correction.



Select this icon or press the [F5] key to toggle the speaker on or off.



Select this icon or press the [+] key to increase the volume of the speaker inside the chamber.



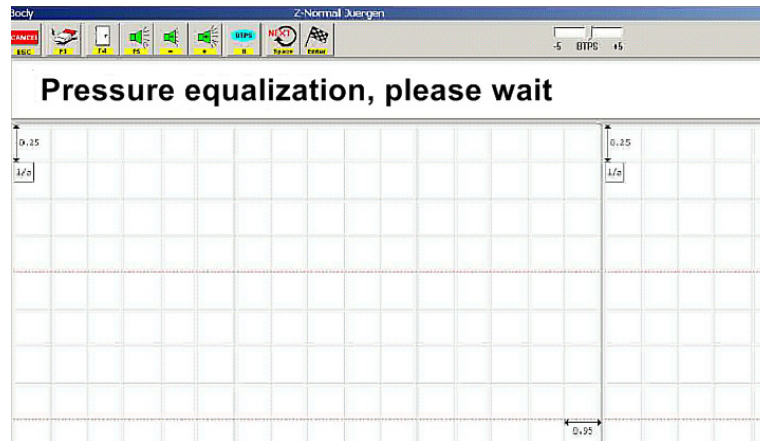
Select this icon or press the [-] key to decrease the volume of the speaker inside the chamber.

4.9.2.4.2 Performing the Measurement

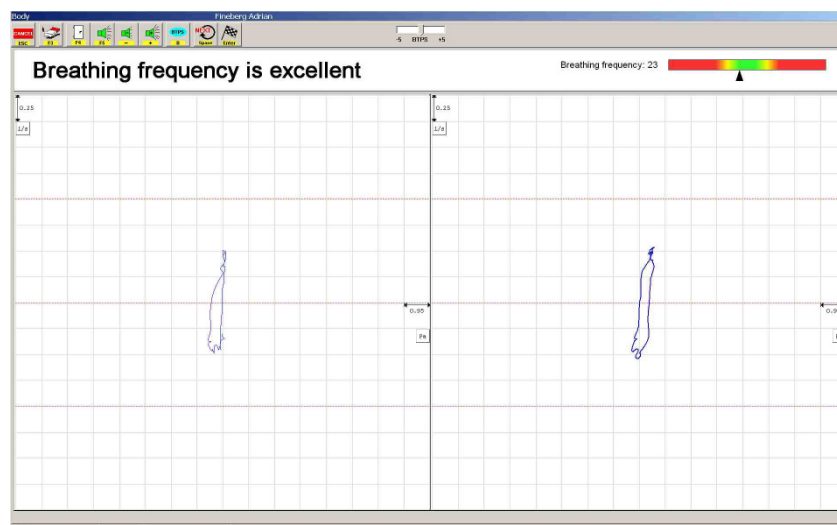
- After selecting the  Button the system checks if the door is closed and all magnets are locked. If not, a window with a warning is issued and the programme does not proceed.



- A sensor detects the door closing and automatically the pressure equalisation of the chamber starts. A corresponding message is displayed in the upper left corner of the window. When complete, the ventilation valve will close and the measurement will begin.



- The patient applies the noseclip, and forms a tight seal around the mouthpiece with his or her lips and starts breathing with a frequency about 25 breaths per minute.



- The breathing frequency bar gives an indication of the patient's current breathing rate. A corresponding message is displayed in the upper left corner, when needed instructing the patient increase or decrease their rate.

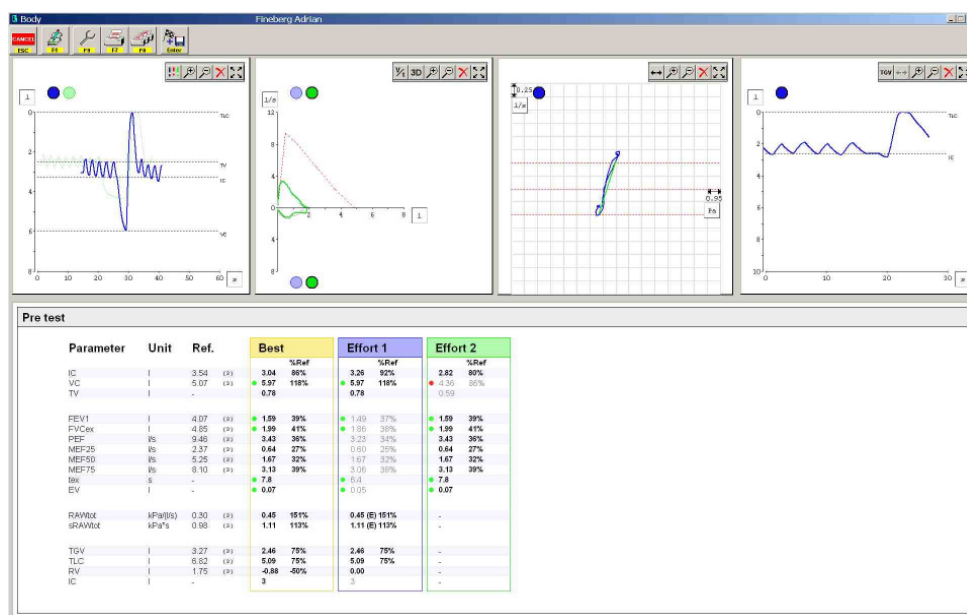
The currently measured loops are displayed in the left window. If the patient breathes irregularly or at the wrong frequency, the curves are ignored. After a certain minimum count of valid curves are measured (configured in Setup), the programme computes an average curve, which is displayed in the right window.

- Every click of the  button or press of the [Space] bar starts a new test. Already measured average curves will be displayed in the right window to the left of the current curve in different colours.

Note: Body heat of the patient increases the temperature inside the chamber. This will cause a rise of the pressure. The ZAN530 Body provides a unique method to compensate this drift. This is automatically applied so that no other precautions need to be taken.

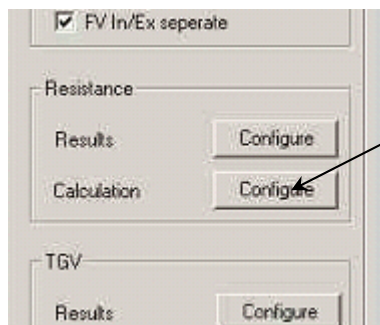
Caution: To ensure reproducibility of the measurement at least 3 independent resistance curves should be acquired.

- Selecting the  button or pressing the [Enter] key terminates the measurement and computes the results.
- The system returns to the overview at the multi measure screen.

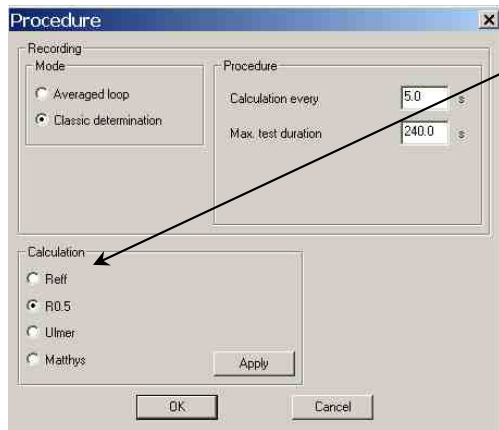


4.9.2.4.3 Editing Resistance Values

Currently there are four different methods implemented to calculate the resistance from the measured curves. The preferred method can be selected in Setup.



Selection of the method of calculation.



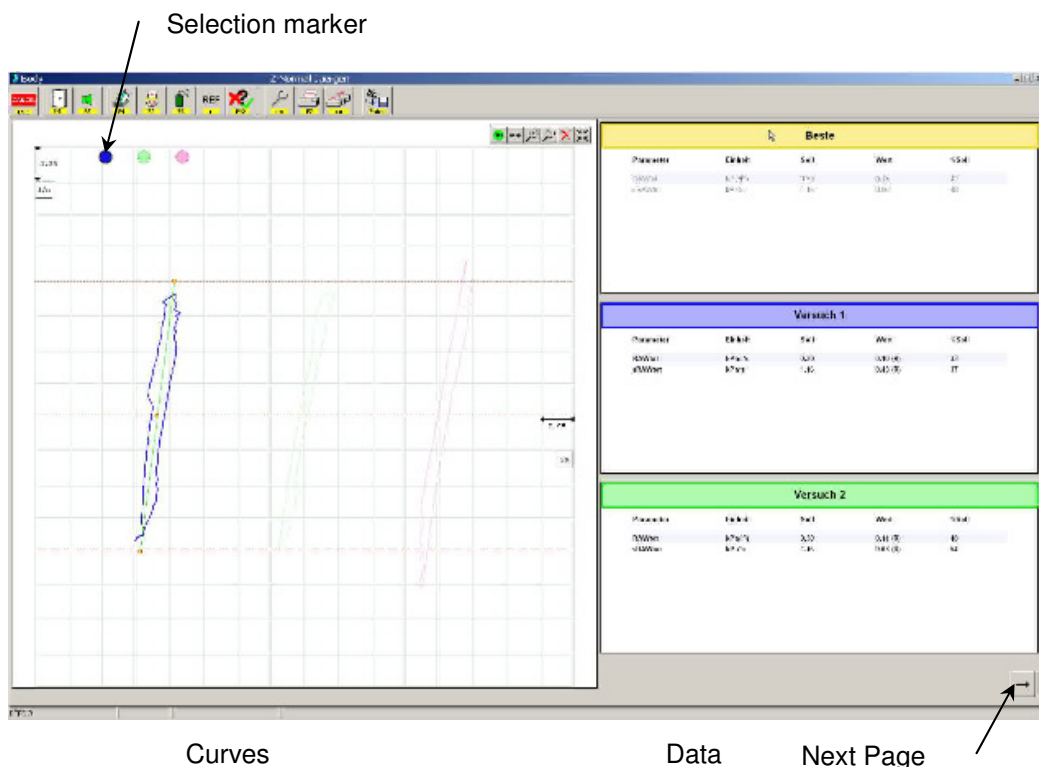
Four different methods are available

- R effective
- R 0.5
- Ulmer
- Matthys

Press [OK] to apply the selected method on the current test.

Press the [Apply] button to apply the method on all tests in the system.

From the multi measure window (the overview) load the measurement into the display window by pushing the  button. The display becomes the edit window now.



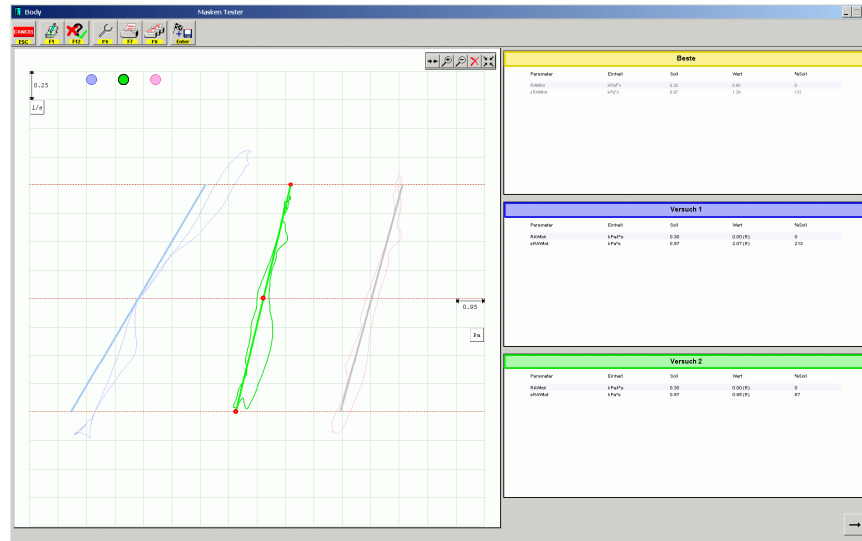
The edit window is split into two areas. Resistance curves on the left and data tables on the right.

Each test is marked with a colour code. The curve to be edited is selected by a click on the corresponding colour dot.

According to the selected method of calculation, the system creates a line of best-fit in the active curve, which represents the measured resistance.

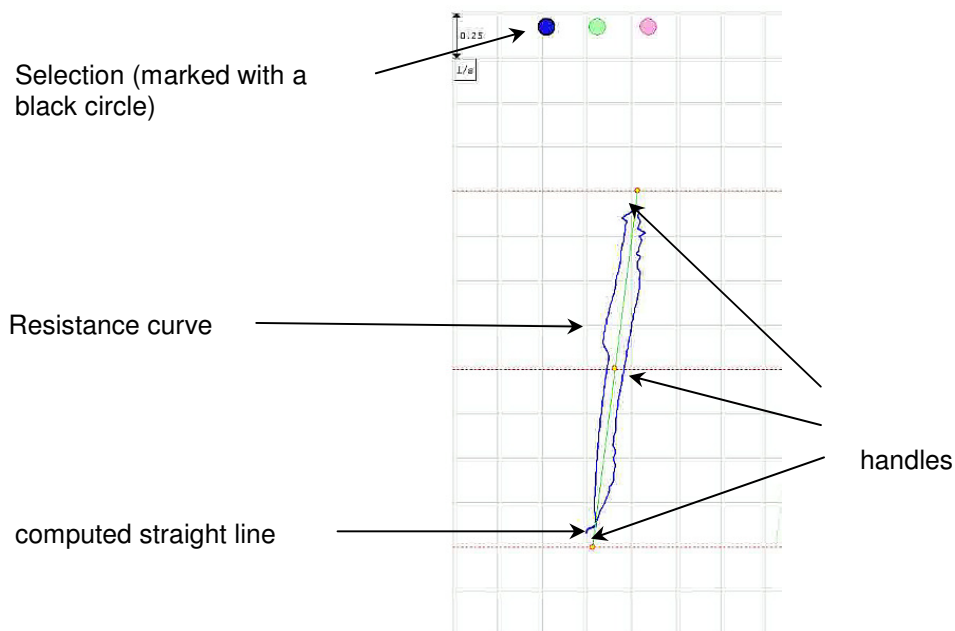
Note: In case the line of best fit should be displayed in all resistance curves, a switch has to be toggled in the WINGPI.CFG configuration file.
[WBODYCOMBI]
ResShowAllRegLines= NO

If the "ResShowAllRegLines" switch is set to "YES" after the start of the programme all lines will be displayed



Please ask our service technicians for help.

The line of best fit has three handles to allow the user to reposition the line.



In order to move the line, place the mouse pointer on one of the handles. To indicate that the mouse

pointer is connected to a handle, it changes its shape:



Press the left mouse button and move the handle to the desired new position.

This technique allows the user to place the line into the best position.

In the "values" column of the corresponding table on the right side of the screen (same colour code), the new values become visible, followed by a question mark in brackets, signifying that this value has been modified manually (unmodified values show a character in brackets indicating the preferred method of calculation has been applied).



Closing the window by selecting the  button returns to the overview. Alternatively the user can use options from the main icon menu on top.

4.9.2.5 Thoracic Gas Volume Measurements

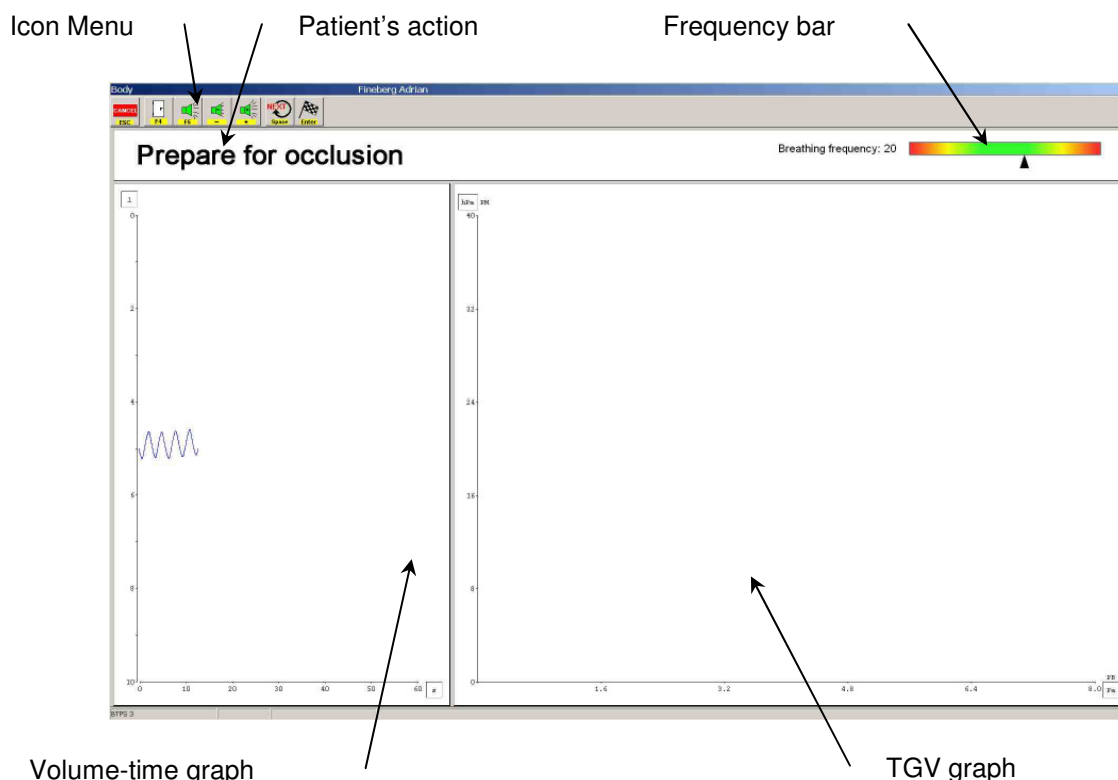
The resistance test should be followed by the TGV measurement. The measurement is initiated when the user pushes the  button in the TGV sub window.

The standard procedure is that this measurement follows directly after the resistance test. The chamber door therefore should be still closed. If the door has been opened in the meantime, for any reason ever, make sure the door is properly closed again and the pressure equalisation is completed.

4.9.2.5.1 The Measurement Screen

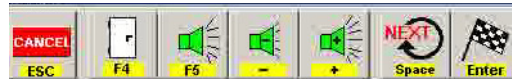
After the programme has been started, the measurement screen is displayed.

4.9.2.5.1.1 Structure of the Window



4.9.2.5.1.2 Symbols of the Icon Menu

The TGV measurement window has its own icon menu, to call particular functions during the test.



A simple click on the icon invokes the function. Hovering over the icon displays a hint.

Symbol definitions

	Select this icon or press the [ESC] key to stop the measurement and exit the program.		Select this icon or press the [ENTER] key to finish the test.
	Select this icon or press the [F4] key to open the door.		Select this icon or press the [SPACE] bar to end the current test and continue with the next one.
	Select this icon or press the [F5] key to toggle the speaker on or off.		
	Select this icon or press the [-] key to decrease volume of the speaker.		Select this icon or press the [+] key to increase volume of the speaker.

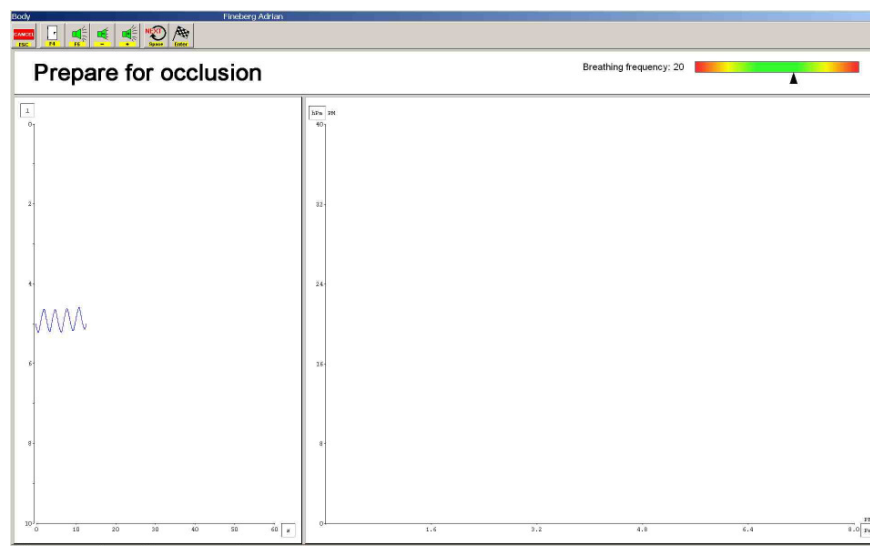
4.9.2.5.2 Performing the Measurement



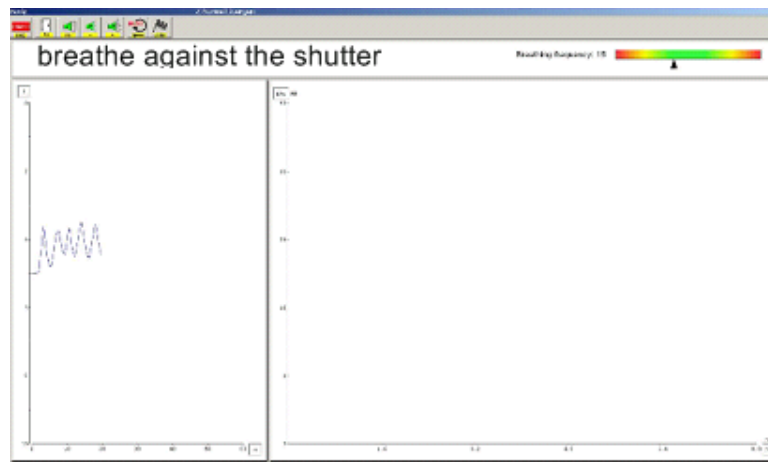
Upon selecting the fourth slot button, the system will recognise the door needs to close and a message will appear in the middle of the screen instructing the door to be closed. This will only disappear when both the magnets have been activated by closing the door. Once the door has been closed and after a short period of pressure equalisation, the ventilation valve will close and the measurement will start. If the door was already closed, no pressure equalisation is needed.

The patient should be instructed to breathe tidally. The frequency bar is again shown in the top right hand side of the screen as guidance.

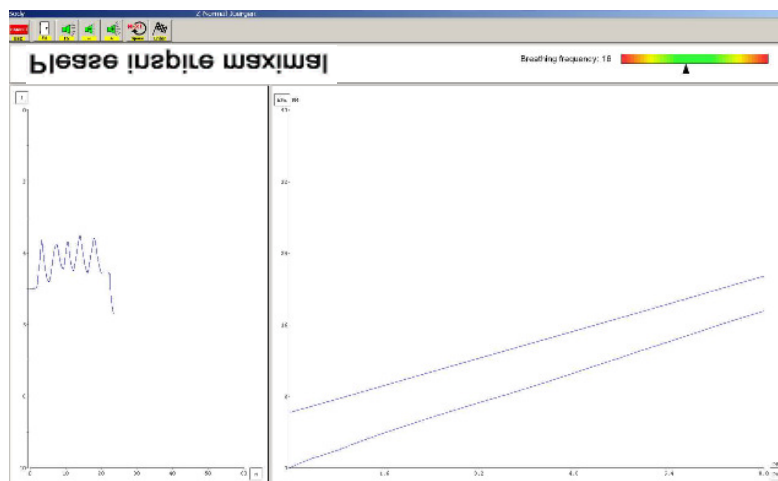
After a few breaths a message warns that the shutter is about to interrupt airflow, to avoid the patient being shocked by the shutter and coming off the mouthpiece.



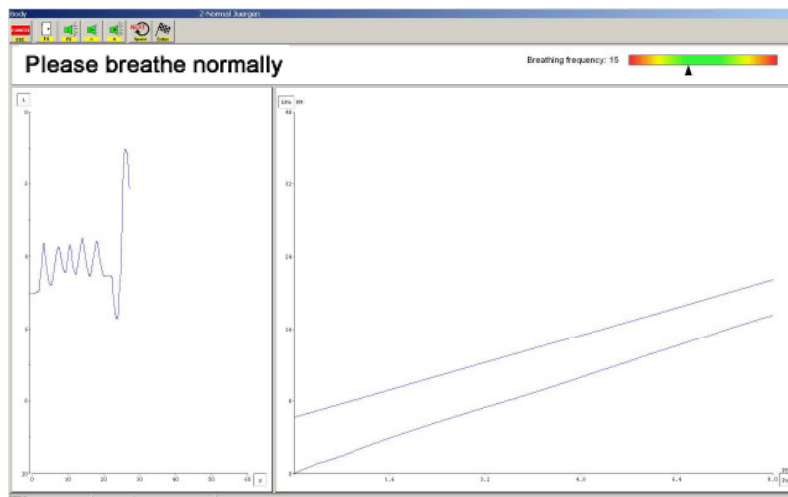
After a predefined number of breaths the shutter will activate and the user must instruct the patient to breathe lightly against the shutter.



After the occlusion, the patient **MUST** do a maximal inhalation to get the corresponding IC. This is needed to calculate the correct TLC.



The system asks the patient to perform this maximum inhalation and then return to normal tidal breathing. The programme automatically recognises that the manoeuvre is complete and ends the test.



Note : TGV and maximum inhalation after occlusion must be performed without interruption to get the corresponding IC. This is needed to calculate the correct TLC.

To save the TGV in the right window and start the recording the next effort, press [SPACE] or select the



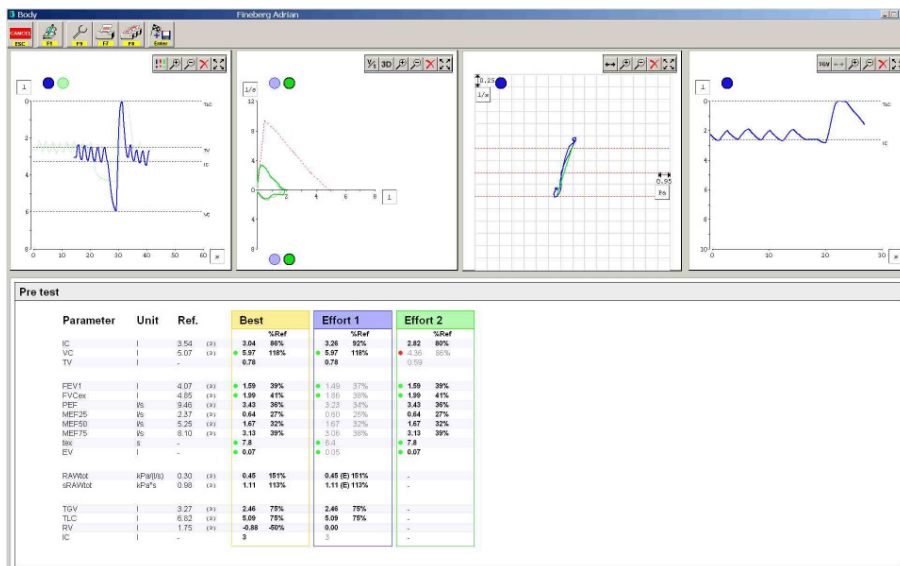
button

To save the TGV in the right window and exit to the main screen, press [ENTER] or select the



Important : The TGV manoeuvre should be measured at least three times to validate the measured values.

Results will be computed and displayed in the results window.



Resistance and TGV calculations use the gradient of the computed straight lines in the graphics.

4.9.2.5.3 Editing TGV Results

The way of editing the TGV results is similar to the one used to edit the resistance (see above). To view

the results and to edit the trace, click the  "Expand" icon.

Two different views are available:

1. The TGV view
2. The IC view

To switch between the two views press the leftmost button in the corner menu marked with either "IC" to go to the IC view, or "TGV" to display the TGV view

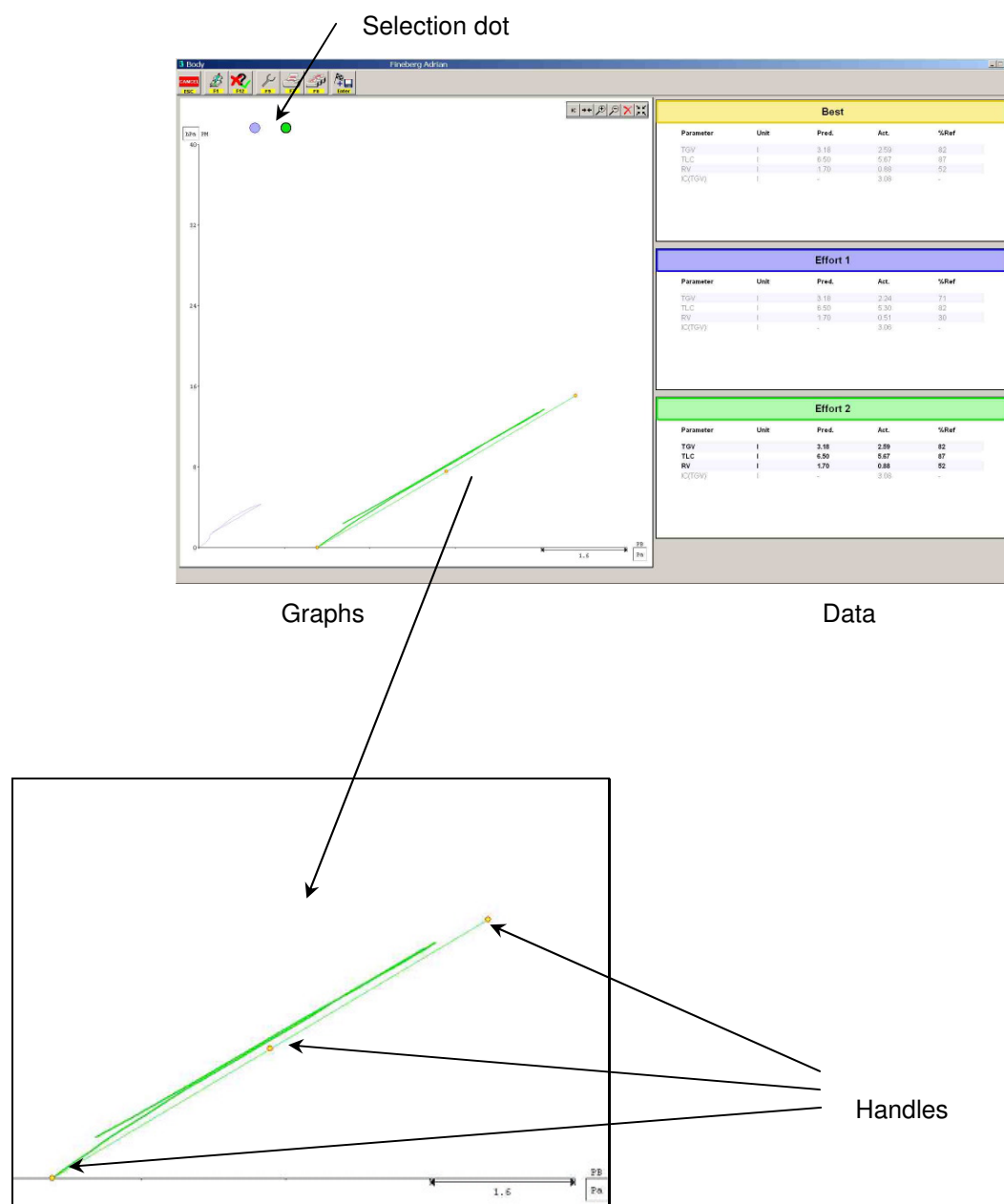


In both views, the edit screen is divided into two areas: graphs on the left and data on the right.

Each test has a unique color code. An effort is selected (activated) by a mouse click to the corresponding color dot.

4.9.2.5.3.1 The TGV View

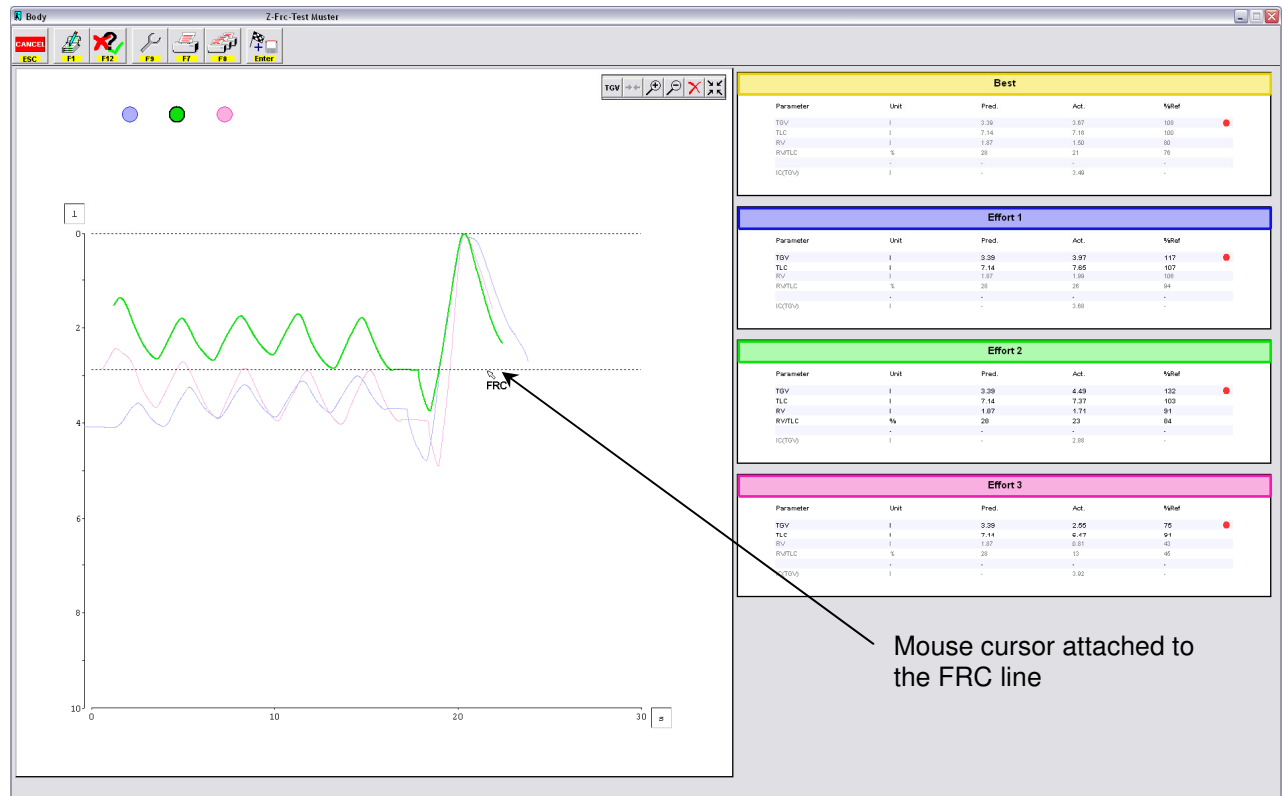
A computer generated best-fit line is placed over the effort. In this view the user can adjust the tangent to correct the value of the TGV.



The line can be turned or shifted using one of the three handles.

4.9.2.5.3.2 The IC View

Additional to the IC line, a FRC line is generated to evaluate FRC during the bodyplethysmography. Reason: In some cases the result of the computer algorithm to position the line does not match the observations of the physician.



The user can adjust the position of the line by placing the mouse cursor over the line and drag it to the desired new position. The mouse cursor is over the line, when it changes its shape to  **FRC**. Press the left mouse button, drag the line to the new position and release the button.

The FRCpleth parameter is also part of the results table.

Effort 1				
Parameter	Unit	Pred.	Act.	%Ref
TGV	l	3.81	4.89	129
TLC	l	8.50	9.07	107
RV	l	2.14	1.98	93
RV/TLC	%	28	22	77
FRCpleth	l	3.81	4.98	131

4.9.2.6 Finalise Measurement

4.9.2.6.1.1 Validate ATS Criteria



In the main window, press the  button or the [F12] key to invoke the automated check of the results against ERS/ATS 2005 standards. The result is displayed in a small report on the screen.

ATS/ERS have provided criteria for the acceptance of the test. The computer will automatically determine whether the criteria for acceptance are met. If an effort is not acceptable, this is shown by a red cross over the corresponding coloured dot. To remove an effort from the selection process right-clicking on a coloured dot also places a red cross. The red crosses can be removed by again right-clicking over the coloured dot.

The fulfilment of ATS-criteria is also visualised on the result table. Green and red dots show for each parameter that is defined by ATS, whether the criteria were met or not. This includes the criteria for acceptance as well as those for reproducibility (only shown when more than one effort has been performed).

4.9.2.6.1.2 Ending the Programme

After the patient has left the chamber, the programme is terminated by pressing the [ENTER] key or



selecting the  button. This will save data and changes in the database.



To abandon test data and changes, select the  button or press the [ESC] key.

4.9.3 Values of the Bodyplethysmography

Acronym	Name	Description	Method
RAWtot	Total Airway Resistance	Total resistance of in- and exhalation	Patient breathes quietly against an open shutter.
RAWex	Expiratory Airway Resistance	Resistance to exhalation	As above.
RAWin	Inspiratory Airway Resistance	Resistance to inhalation	As above.
sRAW	Specific Airway Resistance	Resistance corrected by the volume at which it was measured.	As above.
GAW	Conductance	$1/\text{RAW}$	Computed
sGAW	Specific Conductance	$1/\text{sRAW}$	Computed
TGV	Thoracic Gas Volume	Volume of gas in the thorax at the time of occlusion.	At the start of inhalation the breath is occluded by the shutter
RV	Residual Volume	Volume of gas remaining in the lung after maximal exhalation.	$\text{TGV} - \text{ERV}$
TLC	Total Lung Capacity	Volume of gas in the lung after maximal inspiration.	The patient inhales maximally after TGV measurement.

4.9.4 Specific Problems

Problem:

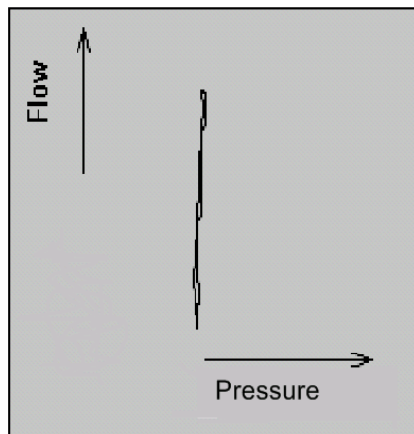
Not all measurements performed with the Body are displayed for review in the Body - VIEW mode. Full bronchial challenge test for instance.

Possible Cause:

No TGV and/or Resistance test performed.

Solution:

Only examinations including the TGV and or Resistance procedure are displayed in the Body – View menu. FV and descendants like bronchial challenge are to be looked up in the Flow Volume – and the Spirometry - View menu.



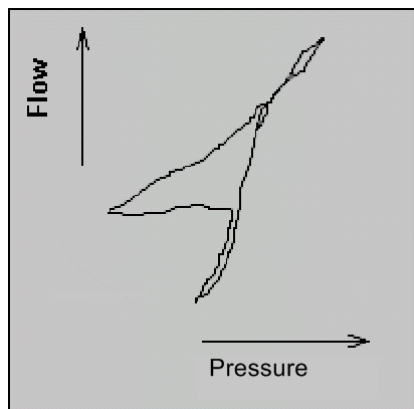
Problem:

The resistance loop is a vertical line.

Possible Cause:

Chamber pressure is not measured correctly or pressure sensor is faulty.

Solution: Close chamber door properly.



Problem:

Chamber pressure shows random fluctuations.

Possible Cause:

Unstable environmental pressure.

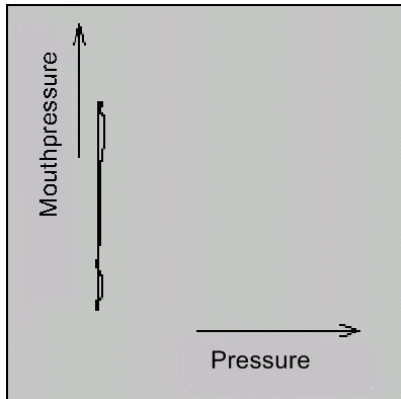
Patient moving inside chamber.

Solution:

Keep windows and doors of the room closed.

Connect pressure equilibration vessel.

Patient should sit more quietly.



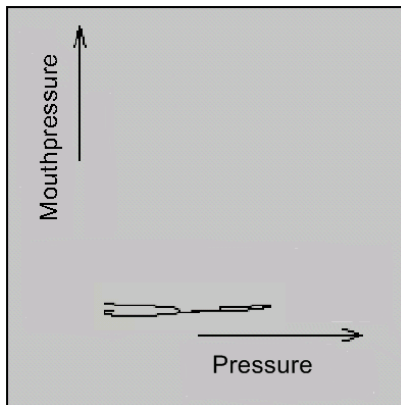
Problem:

The TGV loop is a vertical line.

Possible Cause:

Chamber pressure is not measured correctly or pressure sensor is faulty.

Solution: Close chamber door properly.



Problem:

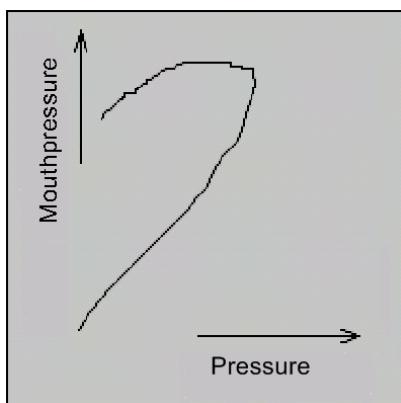
The TGV curve is a horizontal line.

Possible Cause:

Mouth pressure sensor is defective.

Solution:

Exchange ZAN 100 Handy.



Problem:

The TGV line after evaluation is not a line but a curve.

Possible Cause:

The patient did not form a tight seal with his lips around the mouthpiece.

The noseclip was not applied properly.

The mouthpiece was not inserted properly into the ZAN100 Handy.

Solution:

Control mouthpiece and noseclip. Motivate the patient for better compliance.

4.10 Measurement of CO Diffusion and Residual Volume

4.10.1 Basic Principles

The primary function of the respiratory system is gas exchange. Oxygen is transported from the environment through the lung into the blood while simultaneously carbon dioxide is released.

The inhaled air should distribute evenly throughout the lungs and oxygen, once in the alveoli, must diffuse through the alveolar-capillary membrane into the blood.

The effectiveness of gas exchange is mainly influenced by three factors:

1. distribution of air in the lung,
2. perfusion of the lung,
3. state of the alveolar membranes.

There is a volume of air that remains in the lung even after a maximal expiration. Several diseases increase this residual volume and create an imbalance of actively exchanged air and the total volume of the lung. This will reduce the effectiveness of breathing.

Measurement of the diffusion capacity and the residual volume therefore give an estimation of the effectiveness of respiration.

4.10.1.1 Intention of CO Diffusion Measurement

Carbon monoxide diffuses across the lung membrane in a similar way to oxygen. It resembles oxygen in solubility and molecular weight and it binds to the same site on the haemoglobin molecule as oxygen but with a much greater binding affinity. Baseline levels of carbon monoxide in normal, non-smokers are very low. This allows us to easily measure the amount of inspired and, after a breath hold, expired carbon monoxide making possible the calculation of the diffusion capacity or transfer factor.

4.10.1.2 Intention of the RV Measurement

The residual volume is the volume in the lung which can not be expired. Up to a particular level this is physiological. This volume will increase in some diseases. Measuring the residual volume is a good way to estimate the severity and progress of the disease.

4.10.1.3 Measurement Principle

A test gas consisting of known concentrations of carbon monoxide, CO, and methane, CH₄, is inhaled by the patient. Methane is an inert gas and is only diluted by the residual volume. Both methane and carbon monoxide are equally diluted by the residual volume. A further decrease in the expired concentration of carbon monoxide is due to its diffusion across the lung membrane. From the concentration of inspired and expired gases, the transfer factor and residual volume can be calculated.

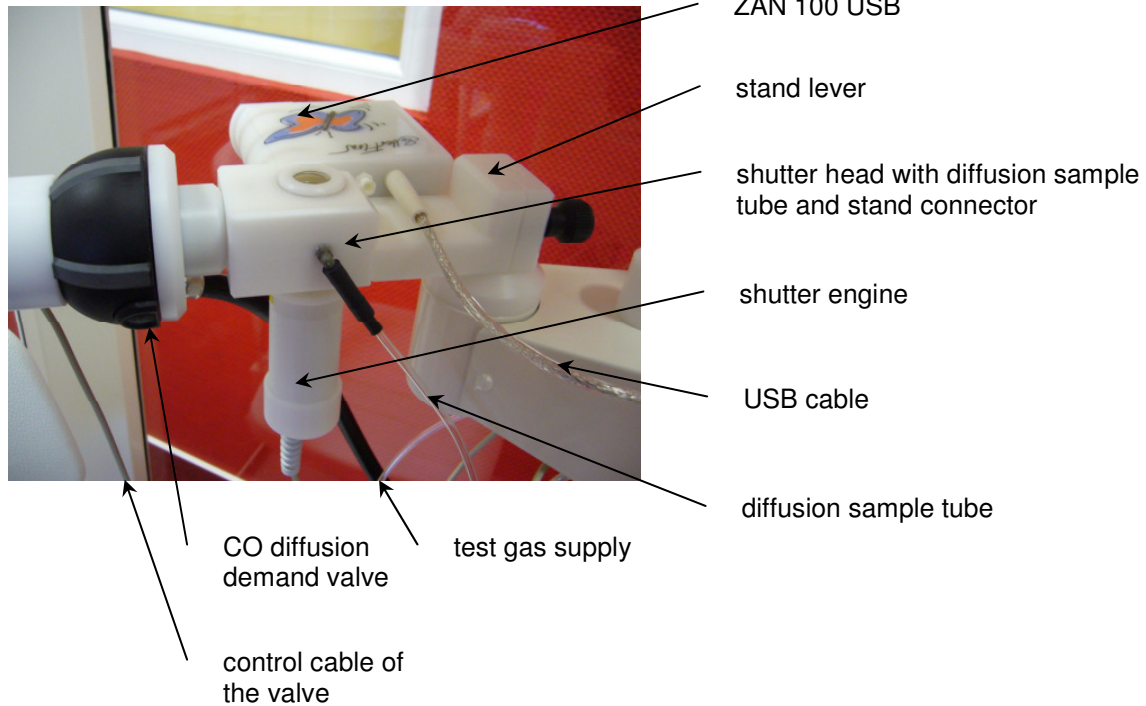
The transfer factor and residual volume are also calculated using the Fast Space balancing method. This method takes the total expiratory gas flux into account and is based on the principle that inhaled inert gas volume must equal exhaled inert gas volume plus residual inert gas volume.

The fast response of the multi gas analyser is utilised and the exhaled methane concentration is plotted against lung volume. Distribution disease is clearly indicated by the shape of this graph.

Literature: H. J. Brandt, J. Bender, R. Lodenkämpfer and E. Wies. Balancing of a "fast space" by means of an alveolar mixing index. Diseases of the Respiratory Tract and Lung, Volume 4, No 3 1978.(p160-168)

4.10.2 Performing the Measurement

4.10.2.1 Assembly of the Device

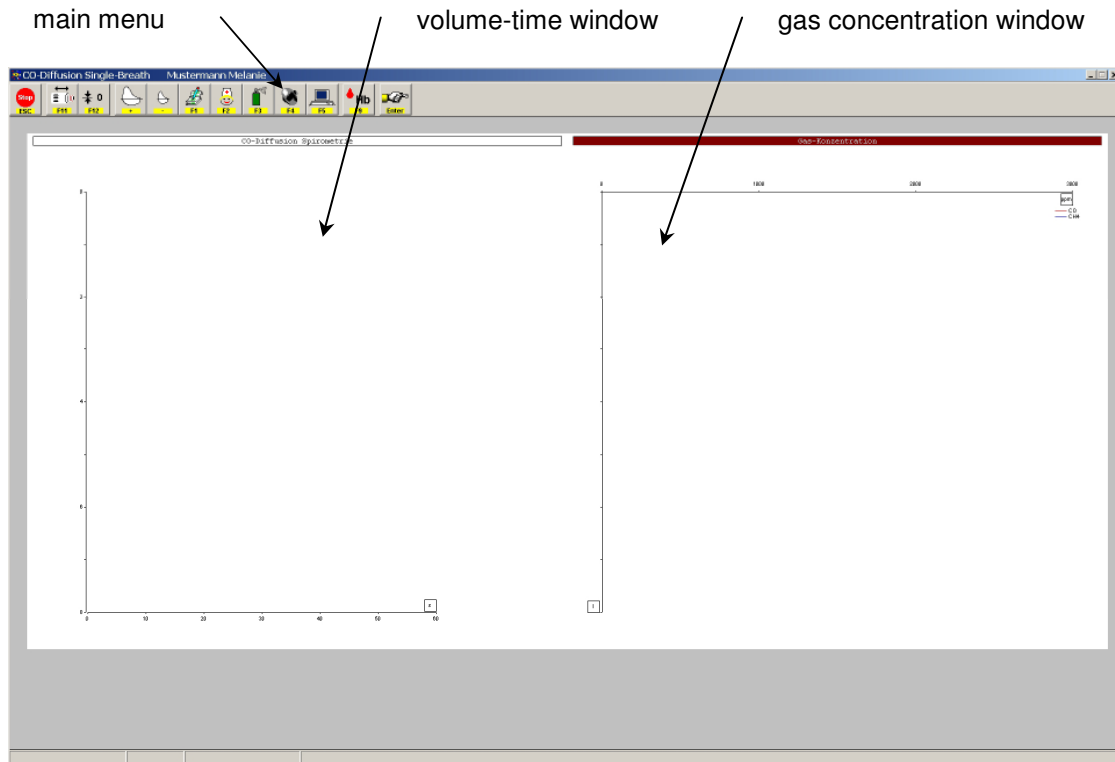


4.10.2.2 Structure of the Measurement Programme

4.10.2.2.1 The Master Screen

After invoking the programme, the master screen is displayed. A timer and additional menu options appear in the measurement screen.

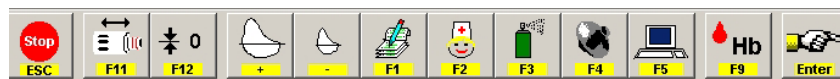
4.10.2.2.1.1 Structure



4.10.2.2.1.2 Menus

The main menu provides access to common functions of the CO diffusion measurement. The contents of the menu are different before and after the measurement. Only valid functions are displayed.

Menu before Measurement:



Menu after Measurement:



Symbol Definitions

	Select this icon or press the [ESC] key to stop the measurement and exit the program.		Select this icon or press the [F2] key to change the user.
	Select this icon or press the [F9] key to input the actual Hb and HbCO concentration.		Select this icon or press the [Enter] key to start the measurement.
	Select this icon or press the [F11] key to trigger the shutter.		Select this icon or press the [F3] key to select the medication.
	Select this icon or press the [F12] key to reset the zero offset. (Patient must not breathe on the mouthpiece!)		Select this icon or press the [F4] key to define type of mouthpiece and filter. (Deadspace.)
	Select this icon or press the [+] key to increase scale.		Select this icon or press the [-] key to decrease scale.
	Select this icon or press the [F1] key to enter comments.		Select this icon or press the [F5] key to enter Setup.
	Select this icon or press the [F5] key to start CO edit mode. (Fast Space.)		Select this icon or press the [F4] key to start the inert gas edit mode. (Fast Space.)
	Select this icon or press the [F8] key to start residual volume edit mode.		Select this icon or press the [F6] key to toggle result window.
	Select this icon or press the [F7] key to start report printing.		Select this icon or press the [F9] key to save the entry.

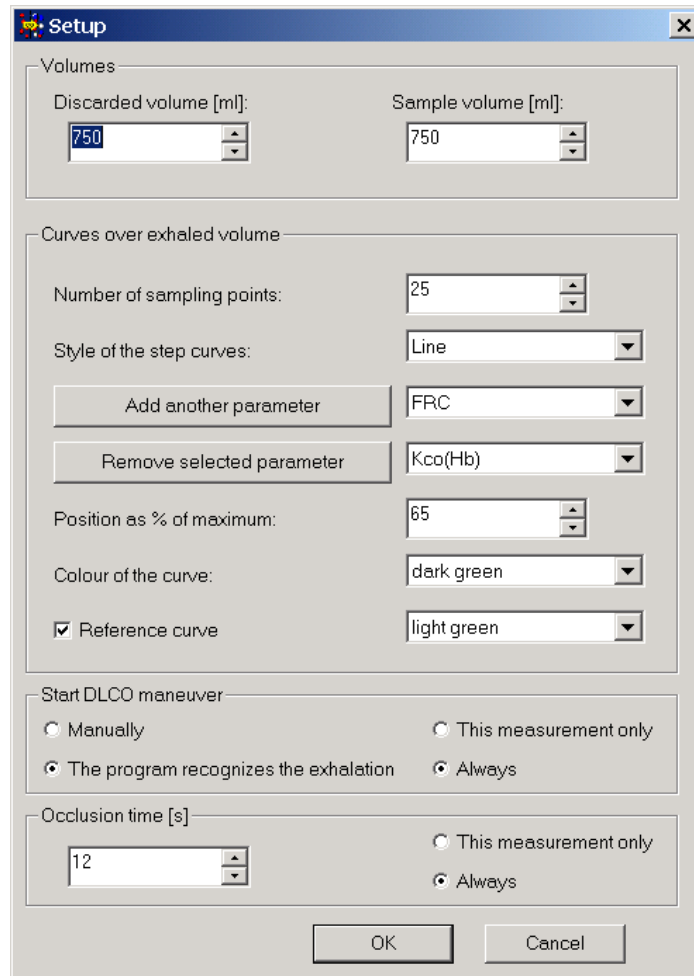
4.10.2.2.2 CO Diffusion Set up [F5]



Pressing the [F5] key or pushing the  button opens the CO diffusion test set up dialogue. This dialogue allows to change the display and a few test parameters to be modified either for the next following test or permanently.

The dialogue is organised in four sections.

- Volumes :
modify the volume to be discarded before sampling and the volume to be sampled for measurement
- Curves over exhaled volume
Add, remove or modify the display style of the displayed curves.
- Start DLCO manoeuvre
select the starting mode for the measurement
- Occlusion time
determine the time, the shutter keeps closed to let the testgas diffuse.



Setup

Volumes

Discarded volume [ml]: 750

Sample volume [ml]: 750

Curves over exhaled volume

Number of sampling points: 25

Style of the step curves: Line

Add another parameter: FRC

Remove selected parameter: Kco(Hb)

Position as % of maximum: 65

Colour of the curve: dark green

☒ Reference curve: light green

Start DLCO maneuver

☐ Manually ☐ This measurement only

☒ The program recognizes the exhalation ☒ Always

Occlusion time [s]

12

☐ This measurement only ☒ Always

OK Cancel

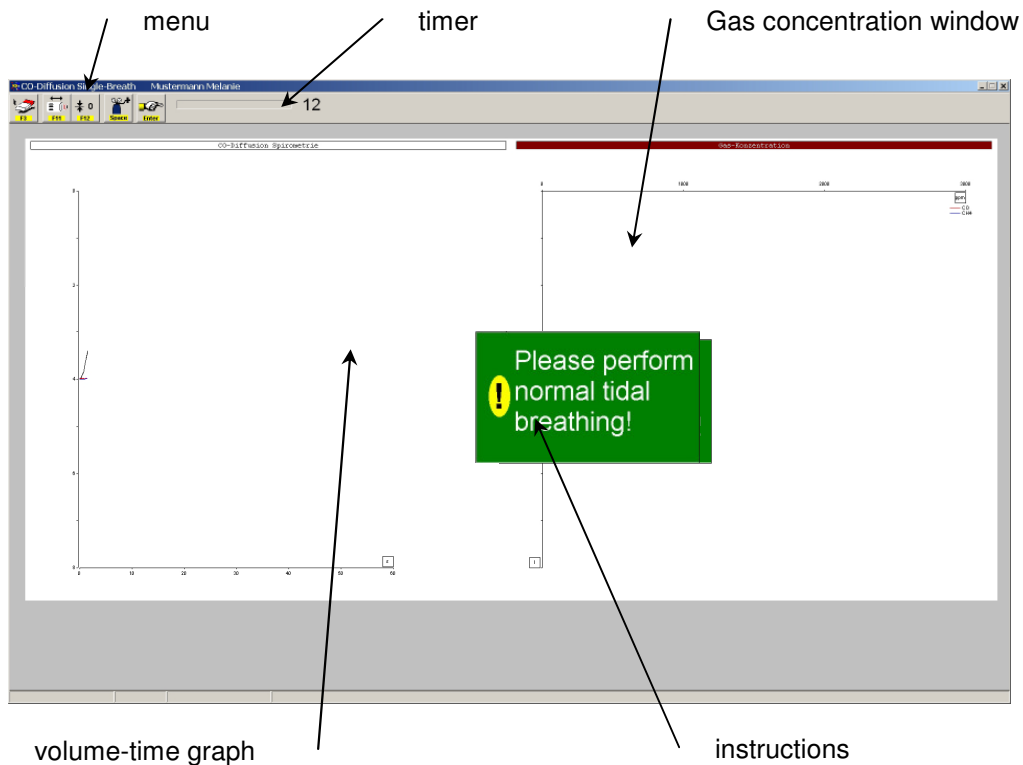
The "Curves over exhaled volume" allows to select the style and colour to be modified. To add a new curve to the display, pick a curve from the drop down list right from the "Add another parameter" and press the button. To remove a particular curve from the display, select the curve from the drop down list right from the "Remove selected parameter" and press the button.

The sections "Start DLCO manoeuvre" and "Occlusion time" have the option to be effective for the next measurement only ("This measurement only") or permanently ("Always").

4.10.2.2.3 The Measurement Screen

The Measurement screen look very similar to the master screen. There's a different menu, a timer is displayed and instructions are given in the centre of the screen as guidance.

4.10.2.2.3.1 Structure



4.10.2.2.3.2 The Menu

The menu of the measurement screen contains the necessary controls to perform the measurement.



Symbol Definitions



Select this icon or press [ESC] to erase the beginning of the test.



Select this icon or press the [F11] key to trigger the shutter.



Select this icon or press the [F12] key to reset the zero offset. (Patient must not breathe on the mouthpiece!)



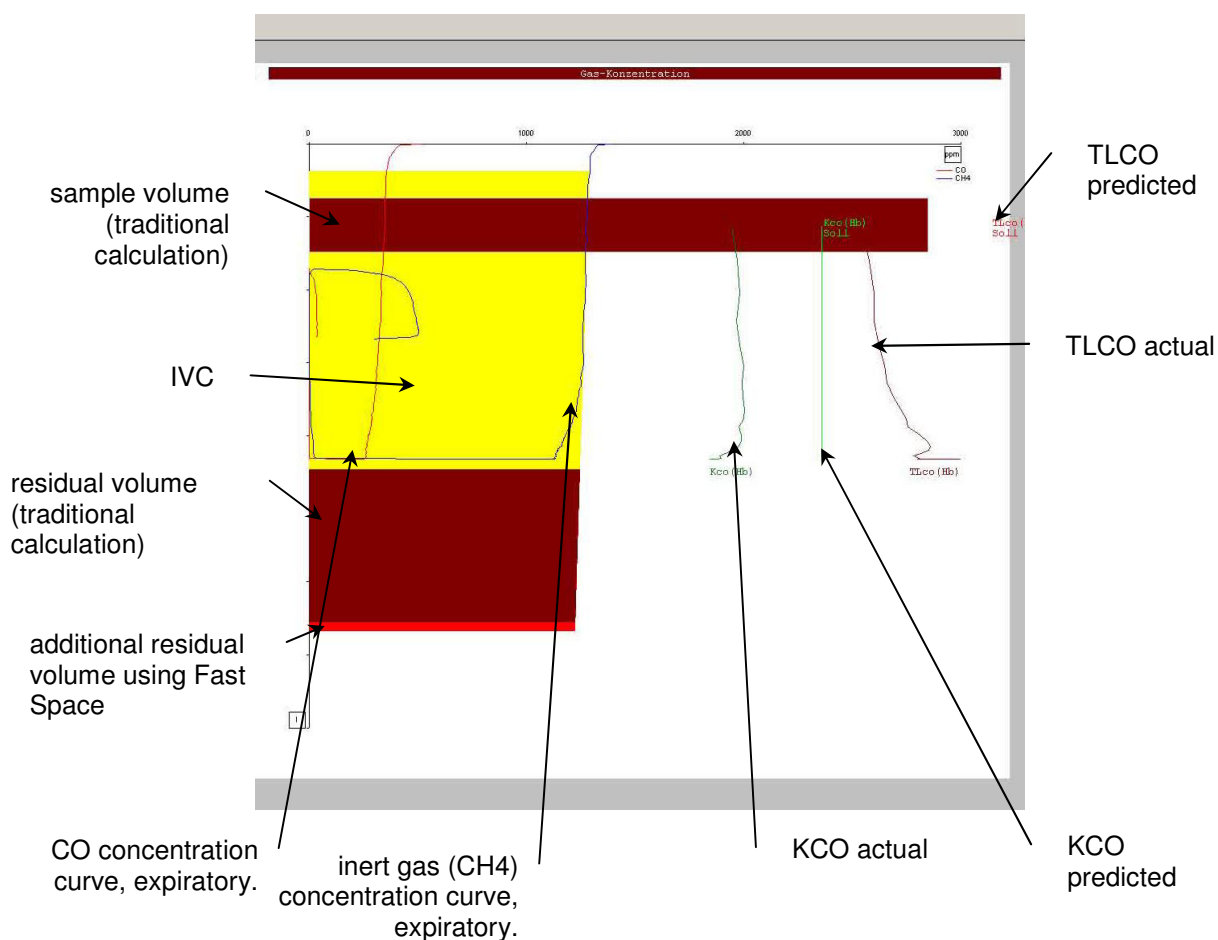
Select this icon or press [Space] to open the demand valve and deliver the test gas.



Select this icon or press the [Enter] key to start the measurement.

4.10.2.2.4 The Result Window

After the measurement, the results in the form of a volume – concentration graph are displayed in the right half of the master window.



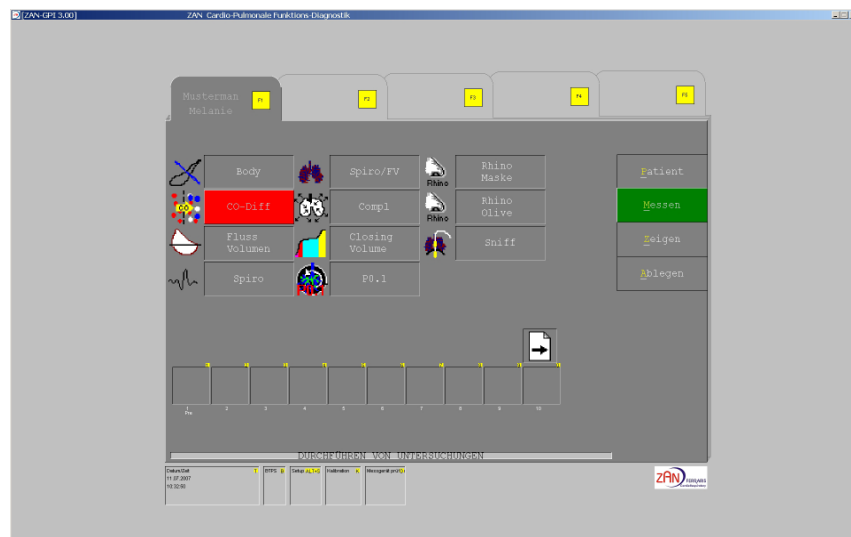
4.10.2.3 Performing the Measurement

Caution : Patients who have consumed alcohol may produce erroneous results since the gas analyser also responds to alcohol.

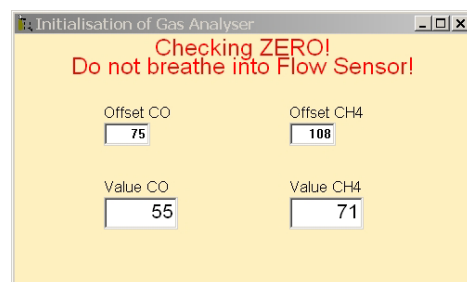
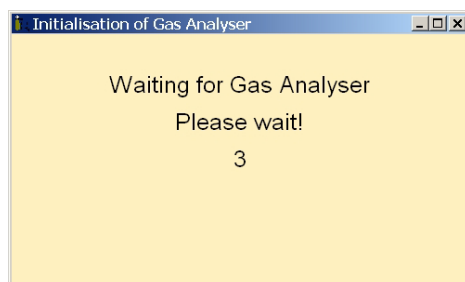


4.10.2.3.1 Start

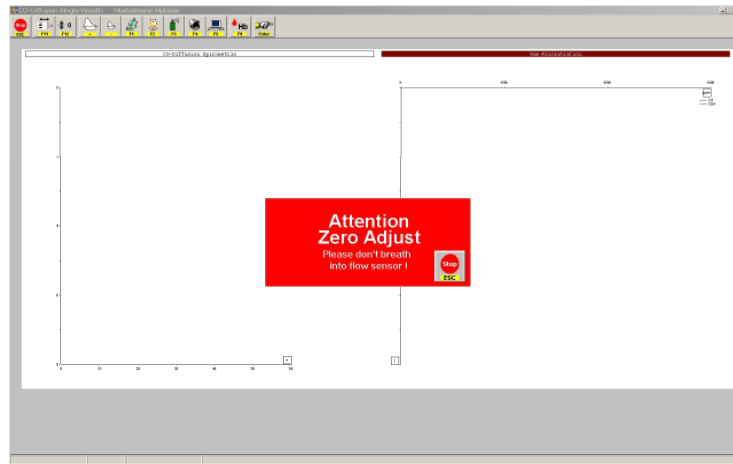
After selecting a patient in the Main Screen, select the measure mode. The CO diffusion measurement programme is invoked by two clicks on the CO Diff button.



Before the programme starts, the analysers must be flushed and calibrated. During this time the user sees the messages below in the center of the screen..



After initialisation the flow sensor must be adjusted to zero. A warning message is displayed during this time.



Caution: The patient must not breathe at the mouthpiece while the flow sensor is adjusted.

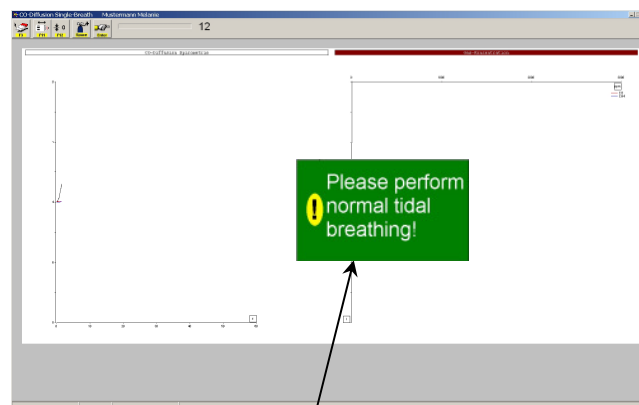
The system is ready, when the Zero Adjust message disappears.

4.10.2.3.2 Preparation

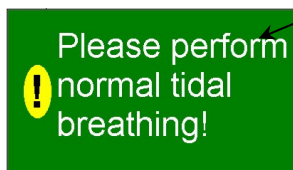
During the test, the patient is guided by the system with a sequence of instructions. This makes the test very easy and it can almost be performed without the user. The directions are displayed in a coloured window in the middle of the screen.



Select the **Enter** button to start the test.



Direction



The measurement begins with regular tidal breathing. If the breathing trace is too erratic clicking on the



button or pressing the [F3] key restarts the sampling. After 5-8 tidal breaths the system begins with the test gas application.

4.10.2.3.3 Test Gas Application

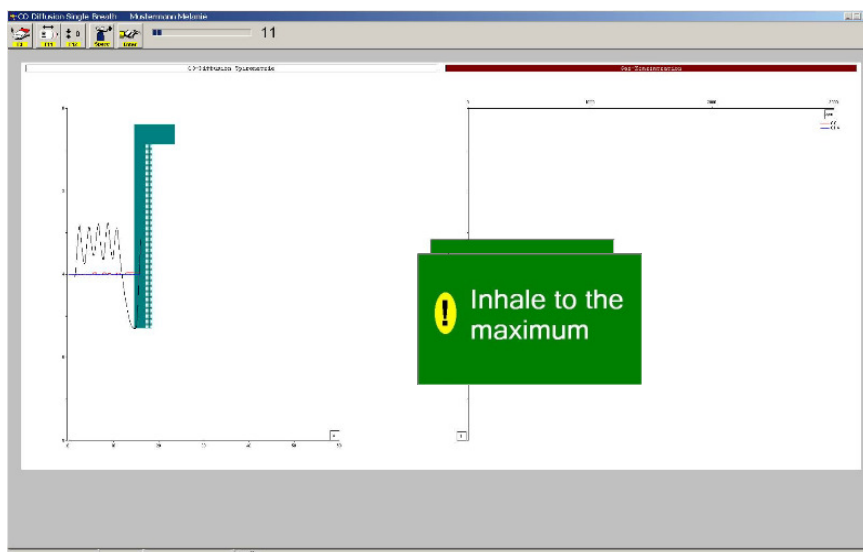
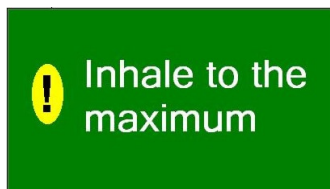
First, the patient is asked to breathe steadily all the way out.

Important : Inhalation and exhalation off the test gas must be performed steadily and without interruption!

The system displays the following messages:

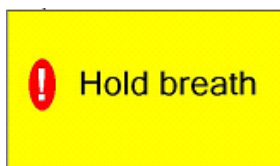


After expiration, the patient is asked to maximally inhale the diffusion test gas..

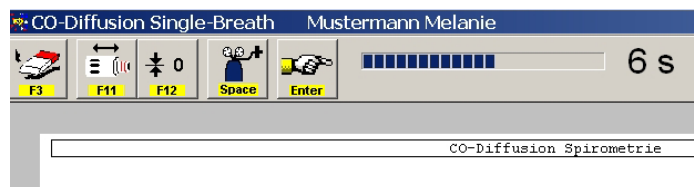


If an SVC has been saved, a green bar appears to indicate this patient's expected inspiratory flow rate and volume. This may also encourage the patient to achieve an adequate inspired volume.

After inhalation, the patient must hold their breath for a preset time ([F5]) to allow the CO to diffuse.



A countdown timer is displayed on the top bar of the window.

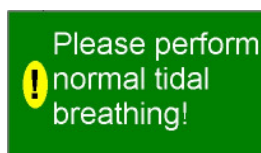


Note: If the patient is unable to maintain breath hold, click on  or press the space bar to immediately reduce the breath hold time to zero and to open the shutter.

At the end of the breath hold time, the patient is again asked to steadily exhale until empty.



To complete the manoeuvre for the Fast Space calculation, the patient should return to normal tidal breathing.



The screen returns from the measurement screen to the master screen and shows the graphical results of the measurement. Numerical results may be displayed by pressing [F6].



Click on the  button or pressing the [F9] key save the results.

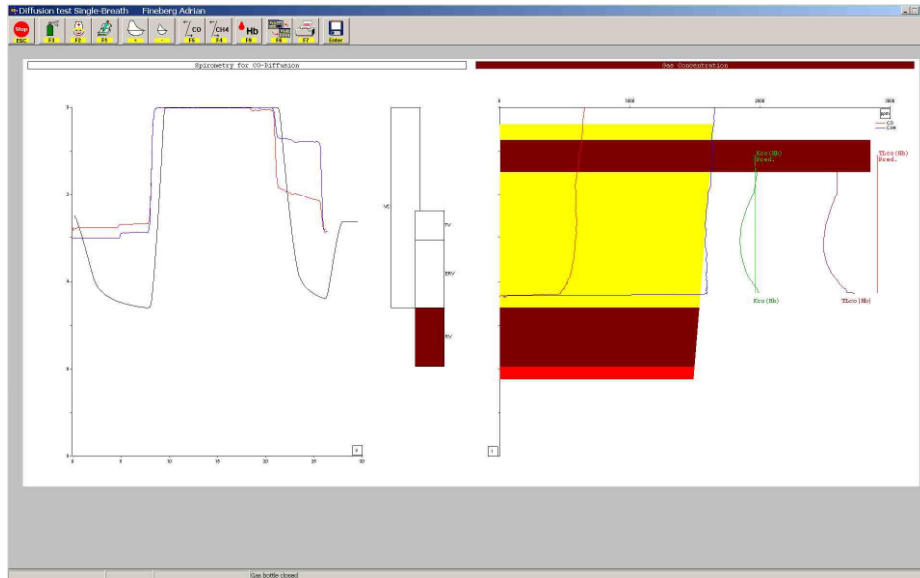
Caution : During breath hold, the patient should be encouraged not to breathe in or out against the shutter (but to relax against it) so as not to alter the intrathoracic pressure and pulmonary haemodynamics. This will affect the results.

4.10.2.4 Results

The results will be displayed graphically and numerically. From this view, the editing of the gas concentration result lines can be done (Fast Space.). The description on how this is done follows below.

4.10.2.4.1 Graphical Display of the Results

The standard view of the results is the graphical display. The left half of the window shows the volume, methane and carbon monoxide traces in different colours.

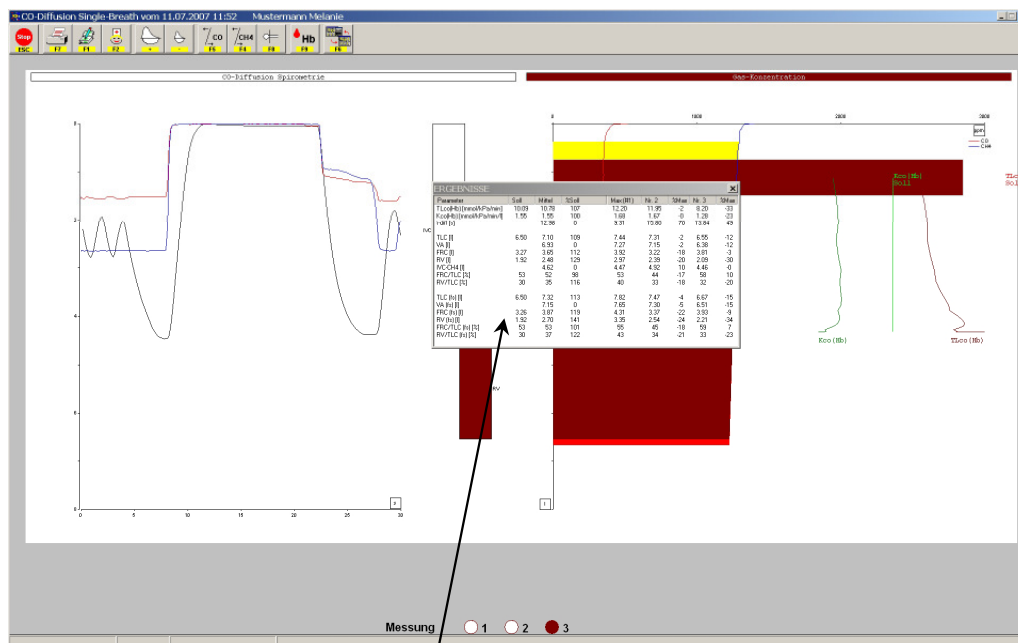


In the right part of the window is the volume-concentration graph showing the computed lung subdivisions and a graphical representation of T_{LCO} and KCO .

4.10.2.4.2 Numeric Display



Selecting the **F6** buttons or pressing the [F6] key invokes the numeric display of the results (or hides it, if it is already visible)



ERGEBNISSE								
Parameter	Soll	Mittel	%Soll	Max (#1)	Nr. 2	%Max	Nr. 3	%Max
TLco(Hb) [mmol/kPa/min]	10.09	10.78	107	12.20	11.95	-2	8.20	-33
Kco(Hb) [mmol/kPa/min/l]	1.55	1.55	100	1.68	1.67	-0	1.28	-23
t-diff [s]		12.98	0	9.31	15.80	70	13.84	49
TLC [l]	6.50	7.10	109	7.44	7.31	-2	6.55	-12
VA [l]		6.93	0	7.27	7.15	-2	6.38	-12
FRC [l]	3.27	3.65	112	3.92	3.22	-18	3.81	-3
RV [l]	1.92	2.48	129	2.97	2.39	-20	2.09	-30
IVC-CH4 [l]		4.62	0	4.47	4.92	10	4.46	-0
FRC/TLC [%]	53	52	98	53	44	-17	58	10
RV/TLC [%]	30	35	116	40	33	-18	32	-20
TLC (fs) [l]	6.50	7.32	113	7.82	7.47	-4	6.67	-15
VA (fs) [l]		7.15	0	7.65	7.30	-5	6.51	-15
FRC (fs) [l]	3.26	3.87	119	4.31	3.37	-22	3.93	-9
RV (fs) [l]	1.92	2.70	141	3.35	2.54	-24	2.21	-34
FRC/TLC (fs) [%]	53	53	101	55	45	-18	59	7
RV/TLC (fs) [%]	30	37	122	43	34	-21	33	-23

The average value of all selected efforts is displayed. Right clicking on a dot corresponding to an effort places a red cross over the dot and removes that effort from the average calculation. (Right clicking also removes the red cross.)

A left mouse click on the dot will display the graph of that effort.

4.10.2.4.3 Editing the Results

The regression lines for evaluation of the diffusion capacity and the residual volume are computed with numeric methods. Depending on the structure of the curves, the resulting line may differ from the optimum result and the user may want to reposition them. Every line can be moved manually.

Selecting  button or pressing the [F9] key save the edited values.

4.10.2.4.3.1 Editing the inert gas line to evaluate RV

Selecting the  button or pressing the [F4] loads the inert gas line (CH4 = Methane) in edit mode. The line is visible as a thicker green line. The green regression line can be adjusted by clicking on the end of the line with the left mouse button. If you press and hold the mouse button you can move the line along the exhalation curve

If the inclination or the position of the tangent has been changed, the gradient must be faded out

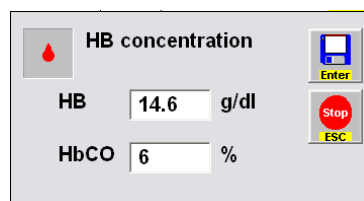
again. By clicking  icon again, the results will be re-calculated.

4.10.2.4.3.2 Editing The CO Diffusion Line

The CO-line is edited by selecting the  buttons or pressing the [F5] key. Now the corresponding line can be moved with the mouse like the CH4 line above.

4.10.2.4.3.3 Considering blood data

Selecting the  icon or pressing the [F9] key opens the blood data entry dialogue.



HB concentration

HB 14.6 g/dl

HbCO 6 %

Enter

Stop ESC

In addition to the hemoglobin value, now the HbCO value (carbonmonoxide blocked fraction of Hb) can be entered for more detailed evaluation. HbCO is respected in the calculation of the predicted values.

4.10.2.5 Important Information

The user should ensure that the patient keeps their lips tightly sealed around the mouthpiece and uses a noseclip throughout the test.

Caution : The patient must not try to breathe in or out against the shutter. This may cause the results to be under- or overestimated.

Important : Patients, who have consumed alcohol shouldn't be tested. The methane analyser is also sensitive to alcohol.

A methane concentration trace changing with the same frequency as the tidal volume is characteristic of a patient in whom alcohol is a constituent gas of their expiration.

Caution : Remember to allow sufficient time between tests for inhaled gases to be washed out. Testing too soon after the previous test will affect the results.

The concentrations of carbon monoxide and methane used in the CO diffusion measurement are very small (0.3%) and the equipment extremely sensitive so the measurement should be performed with due care. Correct technique is important.

4.10.3 Addendum

4.10.3.1 Parameter Definitions

Acronym	Name	Meaning	Measurement Method.
TLCO	Diffusion Capacity or Transfer Factor	Rate of transfer of test gas between the alveoli and erythrocytes in the alveolar capillaries.	In a single breath, the test gas is inhaled and after a defined period of time exhaled.
KCO	Transfer Coefficient	TLCO/VA Uptake of gas per litre of ventilated lung.	As above.
FRC	Functional Reserve Volume	Lung volume at end tidal respiration	Dilution of inert test gas.
RV	Residual Volume	Lung volume which can not be exhaled.	As above.
TLC	Total Lung Capacity	Maximum Volume of the Lung	
t diff	Diffusion Time		1/3 of inspiration up to 50% collected volume (Jones-Mead)
VA	Alveolar Volume	Volume participating in gas exchange	TLC - anatomical dead space

5 Disinfection and Maintenance

5.1 General Disinfection and Maintenance Recommendations

All parts of the ZAN equipment, which can get contaminated by the patients breath are designed for simple and complete disinfection.

Caution: To avoid infections in connection with medical devices, directly contaminable parts have to be disinfected after each patient.

Important: Disinfection must be carried out at low temperature (140°F or 60°C maximum, e.g. with cold disinfectants, cold gas, or plasma disinfection). If you choose an antiseptic solution, you have to make sure that it does not contain high concentrations of chlorid ions and that the material characteristics (of the parts to be disinfected) will not be influenced.

ZAN has tested the following disinfection fluids for their compatibility with the used materials.

Korsolex extra	Bode Chemie
Korsolex plus (Aldehydfree)	Bode Chemie
InstruPlus	Dr. Deppe
EndoStar (Aldehydfree)	Dr. Deppe

for surface disinfection:

Antifect FD10	Schülke & Meier
ST-Tissues	Bode Chemie
SprayIn (Aldehydfreie	Dr. Deppe

(Caution: inflammable at ow temperature (25°C))

Caution: Always consider the recommendations from the disinfectant manufacturers concerning concentration, purpose, and reaction time.

Note: Visible dirt must be removed before actual disinfection..

- ▶ Daily use and disinfection of the parts and the flow sensors will influence their mechanical quality. We strongly advise you to calibrate and maintain the device according to the given recommendations.
- ▶ Some components of the device are connected with tubes. The tubes must not be put into disinfectants. Water droplets have to be removed from the tube connections before putting the device into operation.
- ▶ The complete ZAN system has gaskets (O-rings) for connection. The O-rings should be covered with a thin layer of Vaseline (accessories) to make them slide easily.
- ▶ The tightness of the connected parts is very important, so the O-rings have to be checked regularly. The O-rings consist of silicone and must only be replaced by ZAN replacement O-rings.

- PolyOxyMethylen (POM), Ultraform H2320 by BASF, is exclusively used as the basic material for all white plastic parts.

In addition to the information provided in this section, you should refer to your local hygiene or infection control board for their guidelines on cleaning the medical equipment and/or accessories described in this manual. Other sources of information on cleaning are the American Association of Respiratory Care AARC² and ATS³ clinical practice guidelines

5.2 General Recommendations For Surface Disinfection

All personal should wear protective clothing when handling contaminated or polluted parts.

Inhalation or direct contamination of the skin with the disinfectants can be dangerous to the health of the personal.

Always consider the recommendations from the disinfectant manufacturers concerning concentration, purpose, and reaction time.

Cleaning tissues should only be slightly moistened with the Disinfectant

Warning: The ZAN Electronic modules are not protected from liquids that could get inside the unit. Before cleaning the surface, please unplug the device.



Important: Make sure that no moisture will get inside the device, because this could lead to short circuits or shock hazards and the contacts might oxidise.

5.3 Using Filters

Bacterial filters do not only retain saliva, but also micro organisms like viruses, bacteria, dust and other contaminating substances. The use of a filter (disposable, single use) between mouthpiece and flow sensor guaranties optimum security for the patient, concerning infection protection.

Note: Although the filters are very effective (better then 99%), they can not replace disinfection of the parts of the devices

Flow sensor and the parts of the shutter, described below, should be disinfected at least once per day, even if filters are used with every patient.

There is no difference in the way parts have to be cleaned and disinfected when filters are in use.

5.4 Disinfection Of Particular Components

5.4.1 Small Parts And Materials

All parts that may be sterilised, may also be cleaned using a chemotechnical disinfection in an RDG device.

² AARC Clinical Practice Guideline – Spirometry, 1996 Update, reprinted from Respiratory Care, Vol 41, No. 7, pp. 629-636, 1996.

³ American Journal of Respiratory and Critical Care Medicine, Vol 152, No. 6, pp 2188-2189, December 1995.

5.4.1.1 Paper Mouthpiece

Cardboard mouthpieces are disposed of after use. They are single patient use.



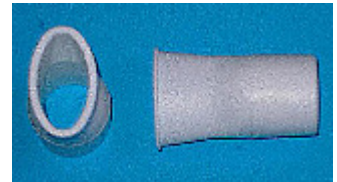
5.4.1.2 Nose clips

Nose clips can be sterilised in 121 °C hot steam (autoclave) and ethylenoxid.



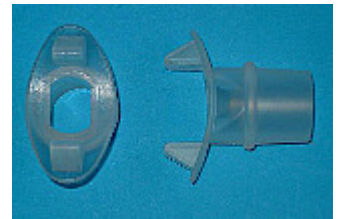
5.4.1.3 Plastic Mouthpiece

Plastic Mouthpieces can be sterilised in 121 °C hot steam (autoclave) and ethylenoxid.



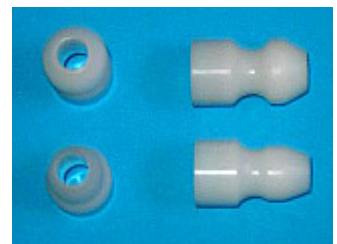
5.4.1.4 Bite Mouthpiece

Bite Mouthpieces can be sterilised in 121 °C hot steam (autoclave) and ethylenoxid.



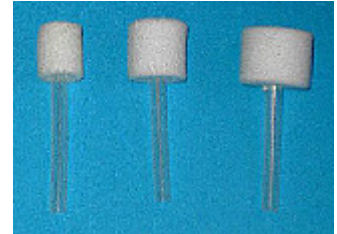
5.4.1.5 Nasal Tips

Nasal tips can be sterilised in 121 °C hot steam (autoclave) and ethylenoxid.



5.4.1.6 Nasal Adapter

Nasal adapters can be sterilised in 121 °C hot steam (autoclave) and ethylenoxid.



5.4.1.7 KoKo Moe Filter

Filters have to be disposed of after use. They are single patient use. For replacement use only ZAN certified filters.



5.4.1.8 Olive Holder

Olive holders can be sterilised in 121 °C hot steam (autoclave) and ethylenoxid.



5.4.1.9 Adapter

Adapters can be sterilised in 121 °C hot steam (autoclave) and ethylenoxid.



5.4.1.10 Cleaning and Disinfecting the Breathing Mask

Caution: Breathing mask must be disinfected after every patient. We strongly advise you to follow the instructions of the manufacturer of the mask, which can be found in the original packing.



5.4.2 Disinfecting The Flow Sensor

Caution: The flow sensors can be exposed to a maximum temperature of 140°F or 60°C during disinfection. Higher temperatures could destroy the variable diaphragm on the inside of the tube



To disinfect the flow sensor, the sensor must be removed from the Flowhandy ZAN100 USB body and put into a disinfecting bath.

It is advisable to remove visible dirt before the actual disinfection.

An ultrasound cleaning of the flow sensors should only be carried out when it is necessary because the mechanical quality of the membrane could be influenced.



Caution: To avoid infections in connection with the flow sensor, it must be disinfected after each patient.

Always consider the recommendations from the disinfectant manufacturers concerning concentration, purpose, and reaction time.

- ▶ The inside of the flow sensor must neither be rinsed with a direct jet of water out of the pipe, nor must it be cleaned or touched by mechanical tools. This could damage the sensitive plastic orifice and disturb the correct measuring function.
- ▶ The flow sensor must be carefully dried after disinfection. Before use you have to make sure that there is no more water in the holes.
- ▶ If necessary blow out the holes with compressed air.

Hint: Compressed air in sprayers for medical purposes is available from your dealer.

5.4.3 Disinfection Of The Flowhandy

The Flowhandy ZAN100 USB contains electronic components and may never be plunged into liquids. It is possible to use surface disinfection using pieces of cloth etc.

If carefully applied, a spray disinfection is possible.

The white pressure sensor on the rear side of the device must NOT be sprayed directly.



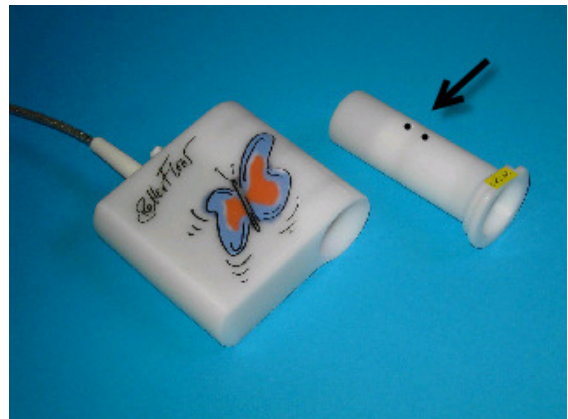
5.4.4 Assembly Of Handy And Flowsensor

Before the Flow sensor is inserted into the Handy again, the O-rings should be covered with a thin layer of Vaseline (accessories) to make them slide easily



Caution: Do not block the holes on the top side of the flowsensor.

Insert the flow sensor in a way that the holes (and the yellow mark on the front rim) are in top position. This will prevent liquid getting inside the device

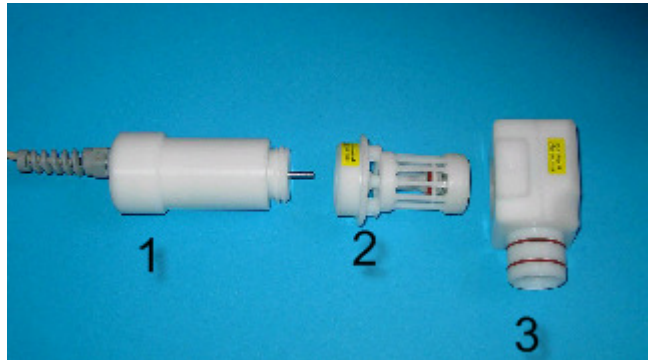


5.4.5 Disinfection Of The Shutter

The Shutter can be dismantled in three parts.

1. Shutter engine
2. Shuttervalve
3. Shutterhead

The Shutter Valve and Shutter Head can be plunged into disinfectant liquid. Spray can also be used.



Important: Do NOT put the shutter engine in any liquid

Caution: The shutter head AND the shutter valve must be disinfected after each patient.

Always consider the recommendations from the disinfectant manufacturers concerning concentration, purpose, and reaction time.

5.5 Disinfection Of The One-Way Valve (CO-Diffusion Option Only)

Caution: Do not plunge the One-Way-Valve into any liquid.
Do not dismantle the One Way Valve.

The One-Way-Valve can be disinfected using tissues. Spray may also be used.

For disinfection, separate the valve from the unit and spray it carefully. Spray the orifice from the patients side.

Dry carefully and completely in a well ventilated area.

During reassembly, the O-rings (gaskets) should be covered with a thin layer of Vaseline (accessories) to make them slide easily.



Caution: In order to exclude any danger in relation with the shutter, the shutterhead AND the shutter valve must be disinfected after each patient.

Use of filters is strongly recommended.

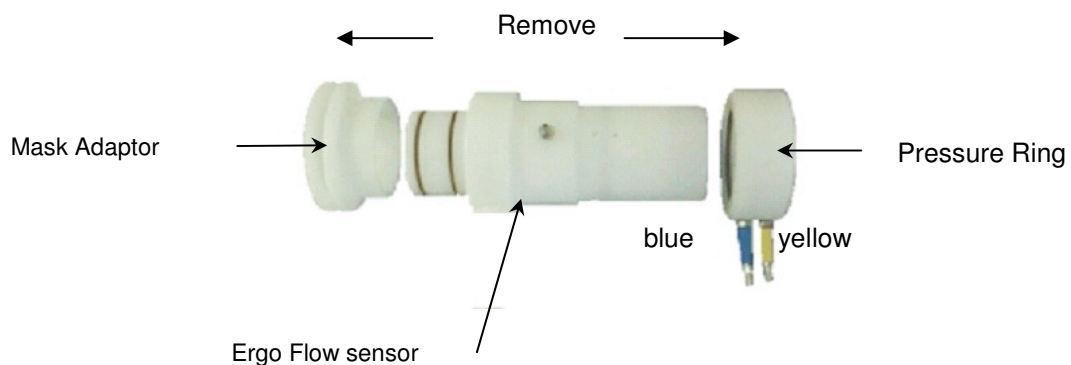
Always consider the recommendations from the disinfectant manufacturers concerning concentration, purpose, and reaction time.

5.6 Disinfection of the Ergo Flow Sensor (ZAN 600 / 680 only)



Assembled Ergo Flow Sensor with adapter and mouthpiece

To disinfect the flow sensor, the pressure ring must be removed. It can be pulled off to the back, seen from the patient's point of view. When you put the pressure ring on the flow sensor again, please consider that the blue connection points towards the flow sensor..



Caution: The blue connecting piece on the pressure ring must point towards the patient.

It is recommendable to remove visible dirt before the actual disinfection.

An ultrasound cleaning of the flow sensors should only be carried out when it is necessary, because the mechanical quality of the membrane could be influenced.

Warning: To avoid infections in connection with the flow sensor, it must be disinfected after each patient.

Always consider the recommendations from the disinfectant manufacturers concerning concentration, purpose, and reaction time.

- ▶ The inside of the flow sensor must neither be rinsed with a direct jet of water out of the pipe, nor must it be cleaned or touched by mechanical tools. This could damage the sensitive plastic orifice and disturb the correct measuring function.
- ▶ The flow sensor must be carefully dried after disinfection. Before use you have to make sure that there is no more water in the holes.
- ▶ If necessary blow out the holes with compressed air.

Hint: Compressed air in sprayers for medical purposes is available from your dealer.

Caution: The flow sensors can be exposed to a maximum temperature of 140°F or 60°C during disinfection. Higher temperatures could destroy the variable diaphragm on the inside of the tube



Hint: The pressure ring does not need to be disinfected. Only pressure is detected at the orifices of the Flow Sensor and no breath flows into or out of the openings back or forth. Transport of germs and viruses or infection of a patient is impossible through this path. We recommend cleaning the pressure ring regularly with wipe disinfection. Care must be taken to not block the holes.

The O-rings should be covered with a thin layer of Vaseline (accessories) to make them slide easily.

5.7 Disinfection And Cleaning The Bodychamber ZAN 500

Caution : There is no protection of the electronics against incoming water or liquids.

5.7.1 Cleaning The Camber And the The Glass Panes

The cabin can be cleaned with ordinary cleansers. Use soft tissues or leather and wipe with hot soapy water.

Make sure the fabric is not wet, but moist and moisture will not get inside the device. If moisture gets inside the device it can cause severe damage to the sensors and electronics.

Do not use aggressive cleansing agents.

5.7.2 Maintaining the Rubber Gasket Of The Door

Never clean the rubber gaskets with aggressive cleansers.

To avoid early ageing of the rubber, it is strongly recommended to at least once per month apply talcum powder to the gasket or use the special rubber maintenance stick, which is available from your dealer.

Visible and cutting cracks of the rubber will influence the seal of the chamber.

Recalibrate the chamber for control and call the ZAN service to replace the rubber gasket if necessary.

5.7.3 Disinfection Of Parts of the Chamber Which Are In Contact With The Patient

Use disinfection tissues or spray for disinfection after each patient. Ventilate properly to avoid irritation to the next patient.

5.8 Cleaning The ZAN Electronic Modules

Warning: The ZAN Electronic modules are not protected from liquids that could get inside the unit. Before cleaning the surface, please unplug the device

The ZAN modules can be cleaned with a piece of cloth that has been moistened in soapy water. Make sure that no moisture will get inside or on the contacts of the device, because this could lead to short circuits or **shock hazards** and the contacts might oxidise.

5.9 Cleaning of the permanent electrodes of suction devices

Permanent electrodes must be cleaned in regular intervals. This is important to ensure good signal quality.

Please refer to the manuals of the manufacturer for detailed information about cleaning and maintenance of the suction device.

5.10 Disinfecting and Cleaning Medical Products of Other Manufacturers

To disinfect medical products, which have not been manufactured by ZAN Messgeräte GmbH (e.g. bicycle ergometer, treadmills, and pulse oxymeter), read the documents accompanying these products.

5.11 Cleaning And Disinfection Of The Touchable Parts in The Environment Of The Patient

For all surfaces in the environment of the patients, a regular cleaning and disinfection with wipe disinfection is recommended. This should be performed according to the common rules of hygiene after visible dirt has been removed.

To avoid any risk, protective clothing during cleaning recommended, especially when the patient is thought to be infectious.

5.12 Cleaning The Computer Equipment

Computer and peripherals are usually not built for the use in an aseptic environment.

We recommend covering the keyboard with an appropriate coverage and cleaning it regularly with wipe disinfection. There are similar covers available for the computer mouse.

The advice for cleaning the cases, tubes and cables are the same as for ZAN electronic modules.

6 Troubleshooting

6.1 General Problems

Problem	Possible Causes	Solution
After starting the measurement, no volume line appears.	- Measurement device is not connected to your PC. - A wrong port was selected. - A wrong measurement device was selected.	- Plug ZAN device into the serial interface. - Select port or measurement device in the set-up programme. - Disconnect the device from the USB port, wait at least 30 sec. reconnect the device, restart the programme.
After starting, the volume line does not run horizontally, even though the patient is not breathing.	- The zero point was not set correctly. - Condensation or Vaseline is blocking the holes of the flow sensors..	- With F12 key or selecting  set the zero point again. - The patient must not breathe on the device while the zero point is set. - Change flow sensor and carry out new calibration.
After starting the horizontal line runs, but breathing is not shown.	- The flow sensor has not correctly been put into the case. - The interface of your PC is in the Power Down Mode. - The O-rings are defective. - The holes of the flow sensors are blocked with water or Vaseline.	- Put the flow sensor correctly onto the case, there must be no gap. - Deactivate the Power Down Mode of your PC. - Replace the O-rings. - Clean the holes of the flow sensor or the holes of the flowhandy.
The volume line is recorded downward with inhalation and recorded upward with exhalation.	Flow sensor has been put into the handy from the wrong side.	Take off the flow sensor and put it into the handy from the right side
The volume-time curve drifts upward or downward during respiration.	- The entered ambient temperature is not right. - The patient is not wearing a nose clip. - The patient does not seal the mouthpiece tightly enough. - The flow sensor is defective or must be calibrated.	- Activate the BTPS entry module with and correct the temperature. - Use a nose clip. - The patient must tightly enclose the mouthpiece or use a different mouthpiece. - Calibrate flow sensor or exchange it

6.2 Body Plethysmograph problems

The door cannot be closed.	1. Door magnets have not	1. Activate door magnets by
----------------------------	--------------------------	-----------------------------

	been activated yet. The door has been deactivated by pressing the security switch.	selecting the door symbol. Press the security switch again.
The resistance curves are wide open.	- The door is not completely closed. - The temperature sensor is defective. - The patient's mouth or nose is not completely closed.	- Check door lock, both magnets have to close audibly. - Call service. - Patient must use nose clip and tightly enclose the mouthpiece.
The resistance curves run vertically..	The cabin pressure is not registered.	- Check cabin door. - Pressure transducer is defective. - Repeat cabin calibration.
The resistance curves run horizontally.	The respiratory flow is not registered.	- The flow sensor or the holes of the handy are blocked. - The flow sensor has not been put far enough into the handy. - The handy is defective.
The TGV curves run vertically.	The cabin pressure is not registered.	- Check cabin door - Pressure transducer is defective.
The TGV curves run horizontally.	The mouth pressure is not registered.	The pressure transducer for the determination of the mouth pressure is defective.
The TGV curves have an oval form..	- The cabin is not completely air tight. - The interruption valve is not sufficiently tight. - The mouth does not sufficiently enclose the mouthpiece.	- Check tightness of the cabin door. - Check tightness of the interruption valve. - The patient must use a nose clip and tightly enclose the mouthpiece.
Only very small TGV curves appear, but the resistance curves are normal.	Poor co-operation.	The patient must breathe more heavily against the shutter

6.3 Diffusion Problems

During test gas inhalation, the air supply is blocked, the patient cannot inhale.	The pressure regulator of the test gas cylinder is not open and/or the pressure connection is not engaged properly to the test gas cylinder.	Open the valve of the pressure regulator. The pressure connection of the breathing valve has to be put in order to make it engage for a second time. This requires much physical effort.
During test gas inhalation, the air supply is blocked, the patient cannot inhale.	Check gas tube, check if the pump runs, check gas analysers	Connect the tube, start the programme again, check the voltage supply of the analysers
The black inert gas line reacts during the tidal breathing.	The patient has consumed alcohol before the measurement or there is some gas left in his lungs from a previous measurement.	Re- schedule measurement.
During test gas inhalation, the black and red gas signal curves do not increase.	Check gas tube, check if the pump runs, check gas analysers	Connect the tube, start the programme again, check the voltage supply of the analysers.
Volume, CH4- and CO gas lines do not start at the same height.	When the zero point was set, there was some gas left in the tube system.	Set zero point , meanwhile the patient must not breathe on the system.
The gas concentration lines heavily decrease while the patient holds his/her breath.	1. The valve system is not tight. 2. The patient breathes heavily against the valve. 3. The connector on the shutter is loose,	1. Check valve system or exchange it. 2. Ask the patient to hold his/her breath and not to breathe against the valve. 3. Tighten the connector on the shutter, but not too tight

6.4 Ergometer Problems

Ergometer or treadmill does not work	1. Devices are not activated or activated after the programme has been started 2. Wrong mode/protocol selected (Note: Bicycle and treadmill are controlled separately) 3. Maybe another user changed the particular ergometer setting on the ZAN PC	1. Activate device and restart programme 2. Select the correct mode / protocol and restart the ergometry programme 3. Set the settings back to the correct values. (Note: there are example settings for Ergoline and Elmed in the addendum. For other types refer to the appropriate manuals in the "PC control" section)
Treadmill does not react	Caution: The patient must leave the treadmill immediately to avoid accidents! Emergency Stop Function is activated.	Reset emergency Stop function. Restart the treadmill If necessary disconnect the device from the PC, restart the system and reconnect the Ergometer.

6.5 Spiro-Ergometry Problems

No volume signal appears while the patient is already breathing.	1. ZAN600 control light is off 2. Flow sensor is not connected	1. Check power cable and switch ZAN 600 on with the switch on the backside 2. Check connection tubes
No O ₂ /CO ₂ gas signal	1. Analysers are not yet ready (Note : The analysers need at least 20 minutes to heat up. Heating time starts with the start-up of the measurement devices) 2. Gas suction tube is not connected to the flow sensor or is interrupted. 3. Wrong gas-calibration or calibration gas cylinder is empty	1. Wait until the analysers are ready 2. Check all tubing's 3. calibrate correctly with a refilled calibration gas cylinder.

Note: To ensure valid measurements, take always care for the following facts

- Always keep volume and gas sensors calibrated to the optimum
- Take care of cleanliness and correct assembly of the sensors
- Watch for tight fit of mask and mouthpiece

7 Software Installation

7.1 Installation

When the system is set up for the first time, install the software and drivers prior to connecting the hardware to the system.

When the software is ready installed, connect the USB plug of your device to a free USB port of your PC system. The device will be recognised by your PC automatically and the appropriate driver will be installed.

Note: If the PC fails to recognise the device: remove the USB plug from the USB port of the PC and wait 30 seconds, then connect again. If necessary, reboot your PC and connect the cable after the reboot . After that, install the ZAN software GP3.xx .as explained below.

7.2 Installation of the ZAN GPI 3.xx Software

Insert the ZAN-CD into your CD ROM drive and the programme starts automatically. Follow the prompts to install the software. If the installation does not start, use Windows Explorer to locate the set-up file (setup.exe) on your CD-ROM and start it manually.

A window pops up. Select the language of the installation and the ZAN Software and confirm by pressing [OK]. Available languages are: English, German and French.



The Install Shield Wizard will be prepared...

...and opened. Click [Continue].

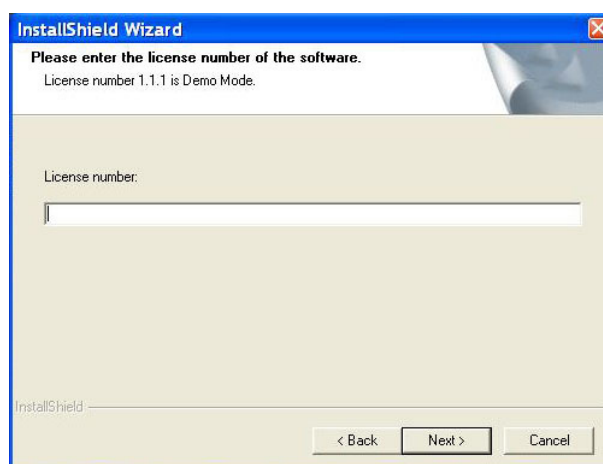


If you agree with the license agreement click [OK].



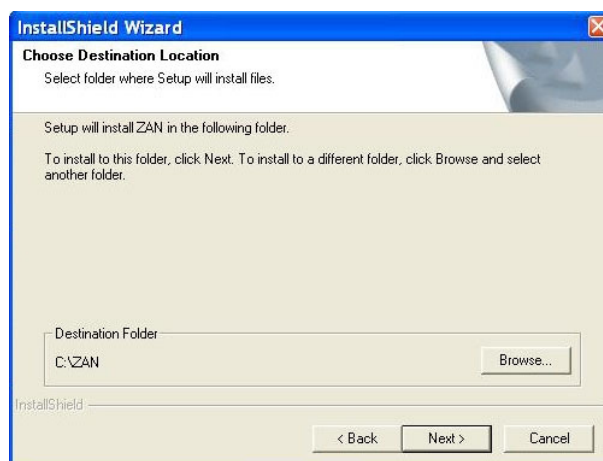
Enter the license number that came with your system and click on [Continue].

If you have the measuring device for demonstration only, you can use the programme in the DEMO mode for 30 days. To use the DEMO mode, enter the license number 1.1.1.



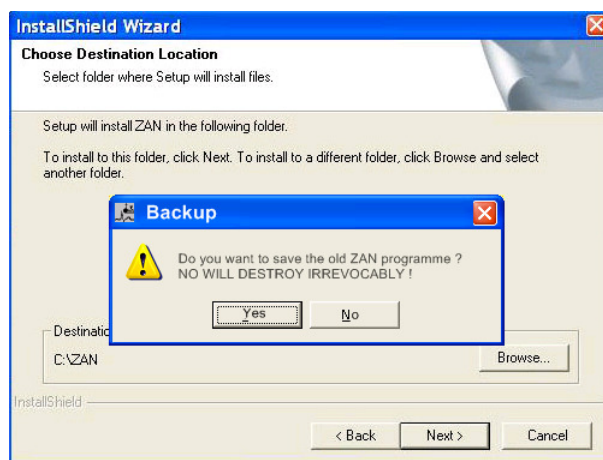
The standard installation directory is C:\ZAN

Caution: Do not change the destination folder. This may cause problems with the software. Contact nSpire Health or your local dealer if you have any questions. If you change the destination folder, nSpire Health cannot be held responsible for possible problems.



If you have selected a directory that contains an older ZAN version, the set-up will suggest you make a backup. Clicking on [Yes] will store the older ZAN installation at C:\ZANOLD\ZAN,<Date>,<Time>.

Clicking on **[No]** will permanently delete the older ZAN installation as well as the archive, and the new version will be installed.



If you have an Internet Explorer Version that is older than the version 6.0, you are prompted to update. It is recommended to install Internet Explorer 6.0 or a newer version.

Only in DEMO-MODE!

If you are installing the DEMO software, select the ZAN Option (measuring device) you want to install.

Caution: If you selected a main device, all options will also be chosen. Therefore, also click on the  symbol on the left, next to the relevant option.



Only in DEMO-MODE!

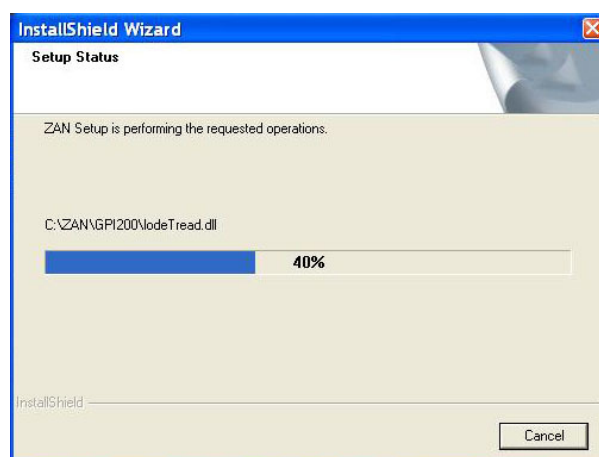
If you are installing the DEMO software, select the + symbol in front of the option. The check mark indicates your choice. If you have selected all measuring devices and options you have purchased, click on [Next].



Check the set-ups before installation and click on [Next]. If necessary, click on [Back] and change the set-ups.



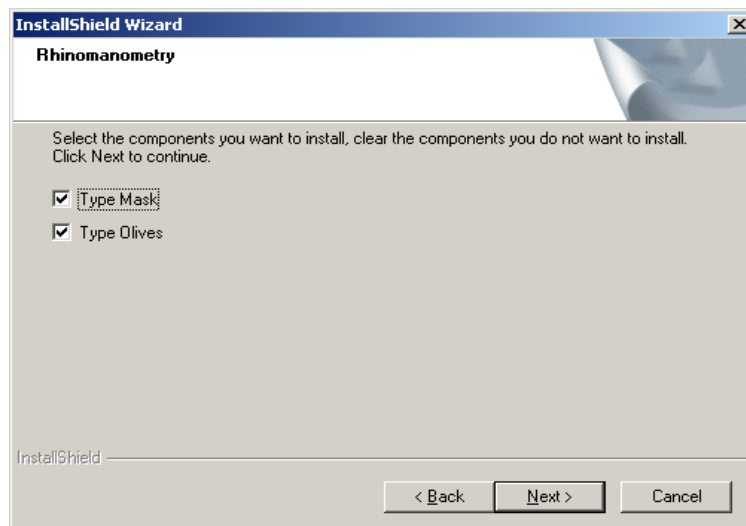
The ZAN programme will be installed automatically.



Only with Option RHINOMANOMETRY!

During the install you will be asked if the Rhinomanometry will be performed with olives or with a mask. Check the appropriate box and press **[NEXT]**.

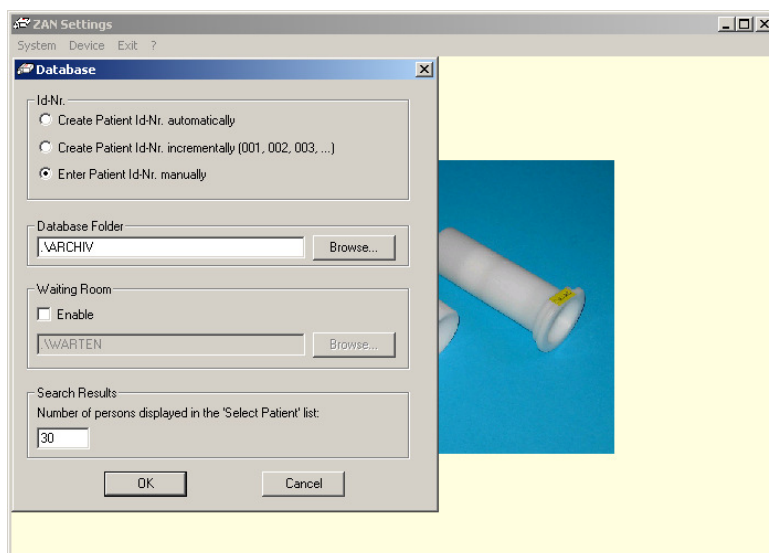
The Installation continues.



Only with ZAN600 and Option ECG!

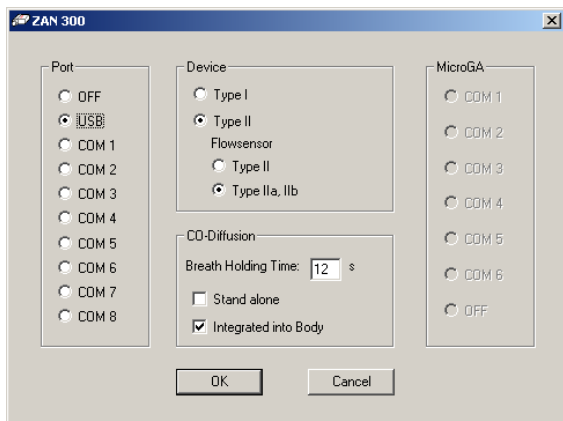
In case the ECG option has been purchased, at this time the installation process branches to the Spacelabs Cardio direct installation. Please refer to the original manual for detailed information about the installation procedure.

Next dialog in the standard installation procedure is the database dialogue.



After finishing the database dialogue, several device settings dialogues pop up, depending on your license. All settings made here can be changed during normal operation using the Set Up option in the main menu.

ZAN300



ZAN 300

Port

- ☐ OFF
- ☒ USB
- ☐ COM 1
- ☐ COM 2
- ☐ COM 3
- ☐ COM 4
- ☐ COM 5
- ☐ COM 6
- ☐ COM 7
- ☐ COM 8

Device

- ☐ Type I
- ☒ Type II
- ☐ Flowsensor
- ☐ Type II
- ☒ Type IIa, IIb

CO-Diffusion

Breath Holding Time: s

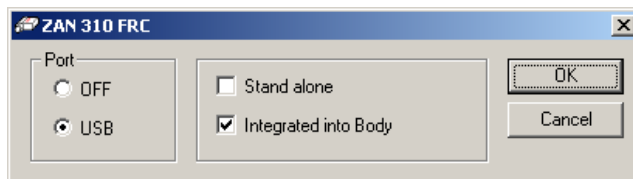
- ☐ Stand alone
- ☒ Integrated into Body

MicroGA

- ☐ COM 1
- ☐ COM 2
- ☐ COM 3
- ☐ COM 4
- ☐ COM 5
- ☐ COM 6
- ☐ COM 7
- ☐ COM 8
- ☐ OFF

OK Cancel

ZAN310



ZAN 310 FRC

Port

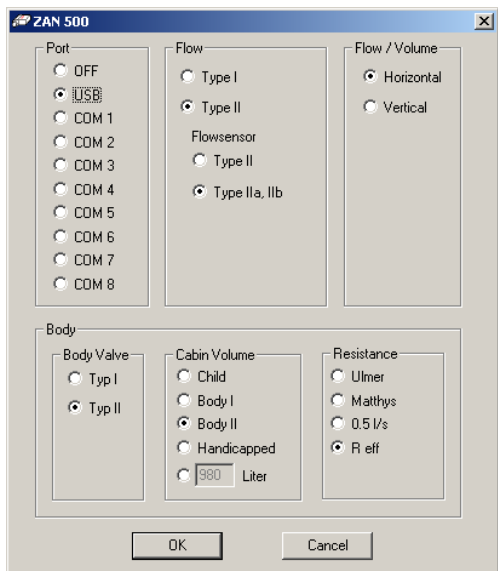
- ☐ OFF
- ☒ USB

☐ Stand alone

☒ Integrated into Body

OK Cancel

ZAN500



ZAN 500

Port

- ☐ OFF
- ☒ USB
- ☐ COM 1
- ☐ COM 2
- ☐ COM 3
- ☐ COM 4
- ☐ COM 5
- ☐ COM 6
- ☐ COM 7
- ☐ COM 8

Flow

- ☐ Type I
- ☒ Type II
- ☐ Flowsensor
- ☐ Type II
- ☒ Type IIa, IIb

Flow / Volume

- ☒ Horizontal
- ☐ Vertical

Body

Body Valve

- ☐ Typ I
- ☒ Typ II

Cabin Volume

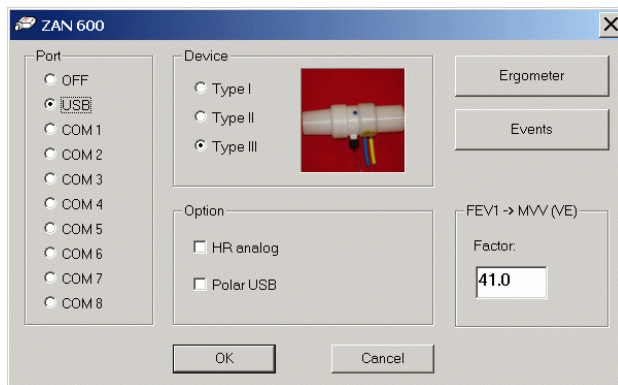
- ☐ Child
- ☐ Body I
- ☒ Body II
- ☐ Handicapped
- Liter

Resistance

- ☐ Ulmer
- ☐ Malthys
- l/s
- ☒ R eff

OK Cancel

ZAN600



ZAN 600

Port

- ☐ OFF
- ☒ USB
- ☐ COM 1
- ☐ COM 2
- ☐ COM 3
- ☐ COM 4
- ☐ COM 5
- ☐ COM 6
- ☐ COM 7
- ☐ COM 8

Device

- ☐ Type I
- ☐ Type II
- ☒ Type III

Option

- ☐ HR analog
- ☐ Polar USB

Ergometer

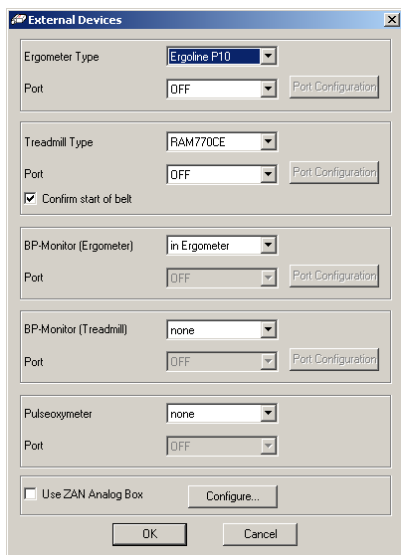
Events

FEV1 -> MVV (VE)

Factor:

OK Cancel

External Devices



External Devices

Ergometer Type

Port

[Port Configuration](#)

Treadmill Type

Port

[Port Configuration](#)

☒ Confirm start of belt

BP-Monitor (Ergometer)

Port

[Port Configuration](#)

BP-Monitor (Treadmill)

Port

[Port Configuration](#)

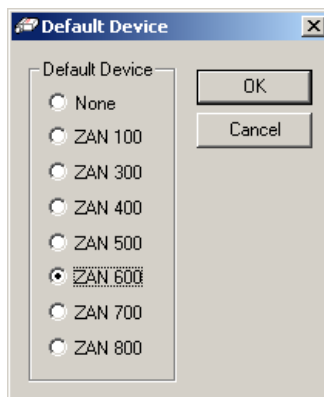
Pulseoxymeter

Port

☐ Use ZAN Analog Box [Configure...](#)

OK Cancel

Set the default device



Default Device

Default Device

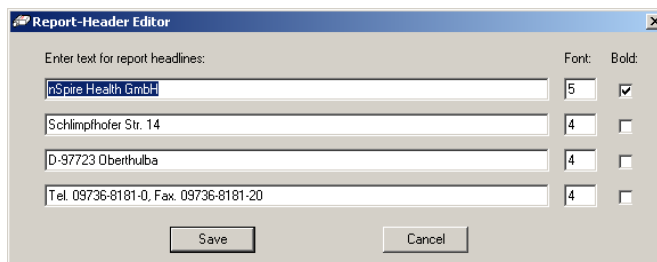
- ☐ None
- ☐ ZAN 100
- ☐ ZAN 300
- ☐ ZAN 400
- ☐ ZAN 500
- ☒ ZAN 600
- ☐ ZAN 700
- ☐ ZAN 800

OK Cancel

After the Installation the Protocol-Header-Editor pops up.

Enter your practice or clinic data as desired.

To store these data, click on **<Save>**.



Report-Header Editor

Enter text for report headlines:

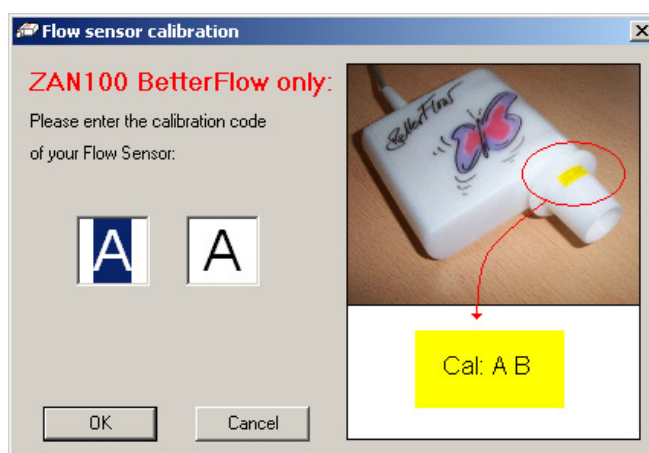
InSpire Health GmbH	Font: 5	Bold: ☒
Schlumpthofer Str. 14	4	☐
D-97723 Obentulba	4	☐
Tel. 09736-8181-0, Fax: 09736-8181-20	4	☐

Save Cancel

Note:

These data can be changed at any time using the Set-up option.

Next you will be prompted to enter the CAL Code of the mounted flow sensor. You find the cal-code on a sticker on top of the frontal rim of the sensor. You find a two character code. Enter the two characters and press [OK]



Flow sensor calibration

ZAN100 BetterFlow only:

Please enter the calibration code of your Flow Sensor:

A A

OK Cancel

Image showing a flow sensor with a sticker labeled 'Cal: A B'.

Note:

The Cal code must be checked on every change of the flow sensor! Change the settings using the option "Calibration" and the chapter Volume calibration.

If not already done, you are prompted to connect the devices to the PC and press [OK]



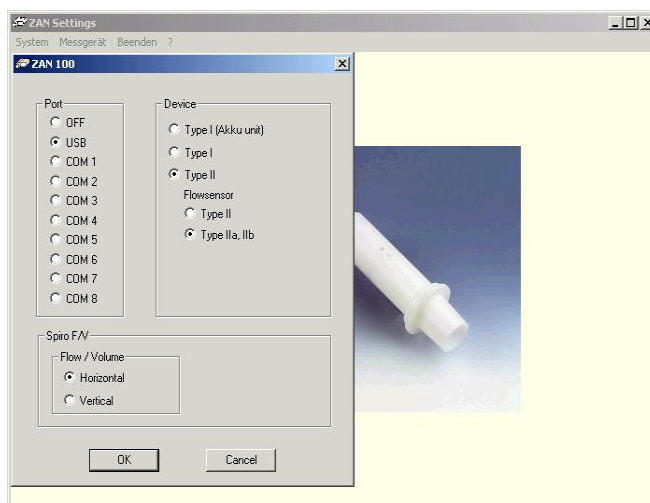
Information

Please connect the device to your computer.

OK

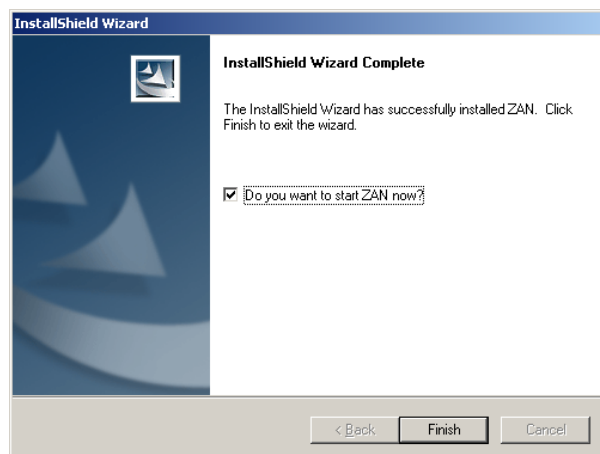
When the ZAN-Settings window pops up, you can configure settings of the several device interfaces and other important settings like printer type, report headlines, database settings etc.

You can change all settings at any time using the S option from the main window.

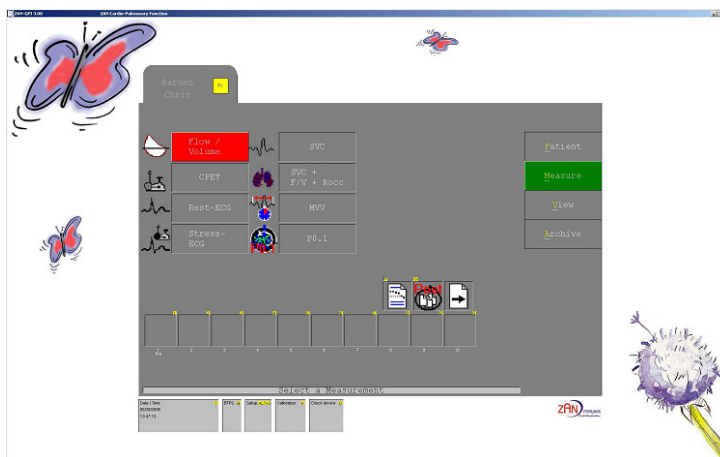


The active device is displayed in the upper left corner. All settings relate to this device only and may vary from device to device.

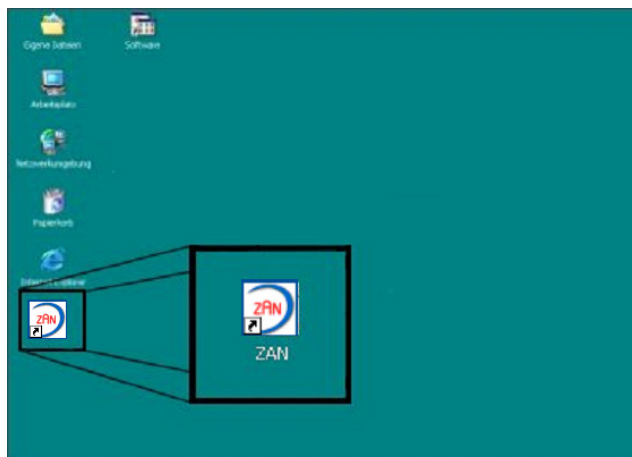
The installation is complete. Click on **[Finish]** in order to close the Install Shield Wizard.



The installation is complete and the software is ready for operation.

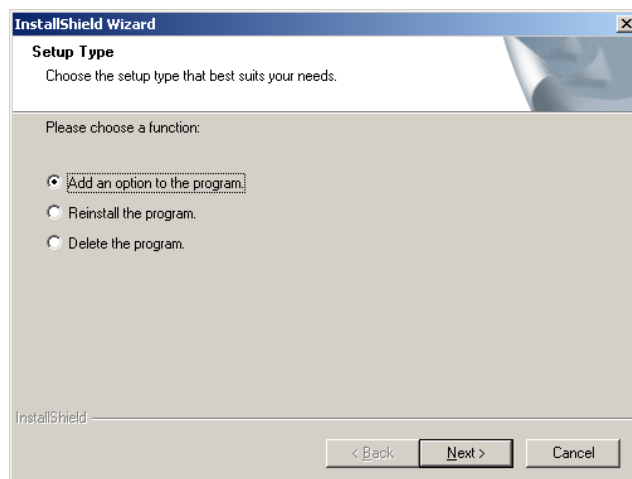


Start the ZAN programme by double clicking on the ZAN icon. Before the first measurement and after the replacement of a flow sensor, it is recommended to perform a calibration.



7.3 Modifying, Reinstalling, or Deleting the Software

To modify, update, or delete the programme, insert the installation CD. The screen to add options to the programme or to completely delete the program is displayed.



Note: Select **“Modify the Programme”** to add new components.
„Reinstall“ is only able to repair existing, install updates or perform a new installation.
 Select **“Delete”** to delete the ZAN programme and all related data.

Demo Mode Only

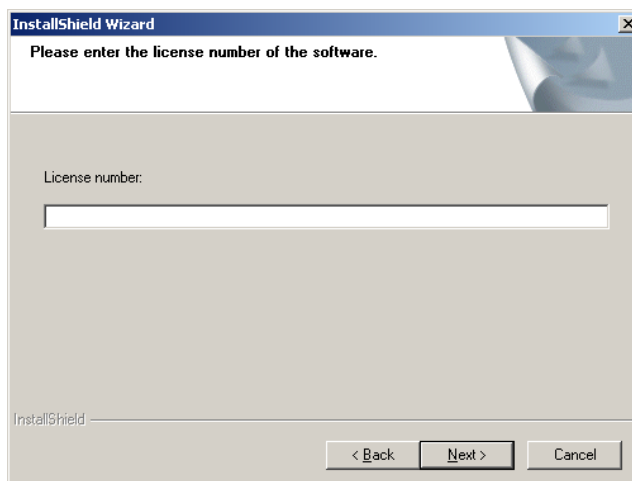
If you chose "Modify the Programme", you will see this window. Now you can install additional options. This programme behaves just like the normal installation programme. Just follow the prompts.



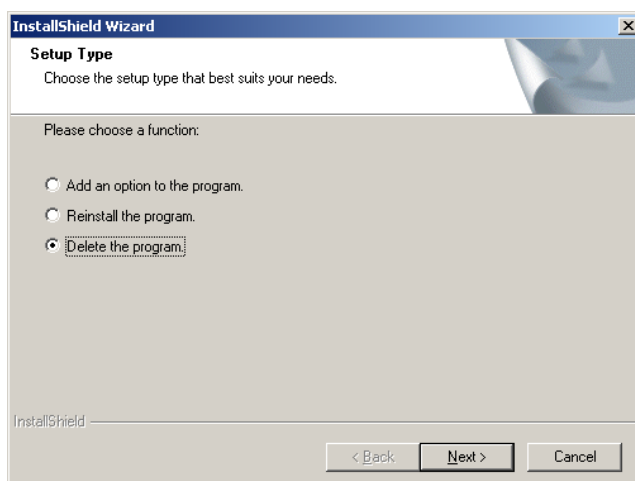
If you choose "Reinstall" you have to enter your new or existing license number. After confirming the rest of the process works automatically.

It is similar to an installation and does not need major changes.

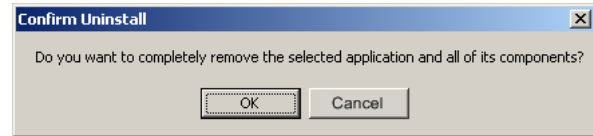
Note: You should use the "reinstall" option only to repair, update or reinstall.



If you select „Delete“, you are prompted to confirm that you are really sure, that you want to delete all programmes and data from your computer.

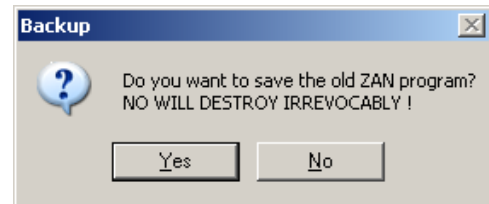


If you want to do so, click on [OK], if you are not sure, click on [Cancel]



If you clicked on [OK], you are prompted to create a backup before deleting. We strongly recommend creating the backup!

If you choose [No] all data related to the ZAN programme, including your settings and the existing patient archive will be deleted! This action is irreversible.



The Deinstall is finished now.

8 Set-up (Customising The Set-up)

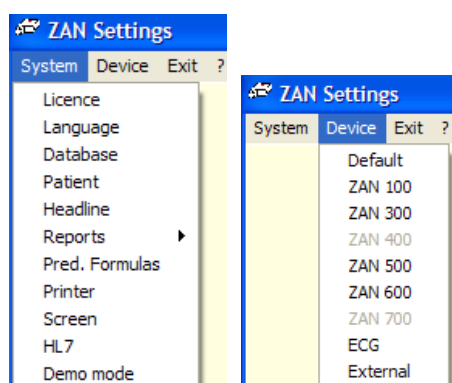
8.1 System Set-up

The Set-up Option can be accessed by

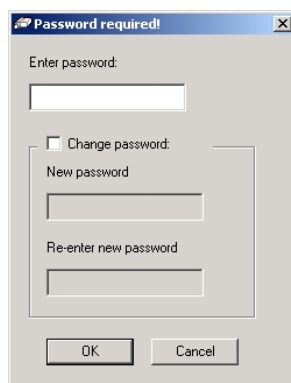
selecting the  icon on the lower portion of the screen.



The Set-up Option enables you to set and change some of the programme settings including the following:



Some parameters are protected with a password. if you try to access or edit such parameters, you will be asked to enter your password with the following dialogue box:



Enter the correct password and click on the [OK] button.

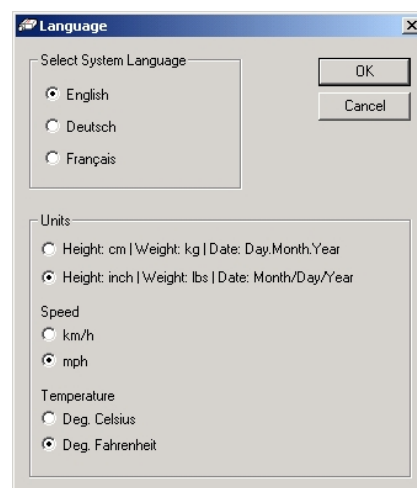
The factory setting for the password is 'Lufu' (entered without the ' '). The entry is case sensitive.

Click on the 'Change Password' check box to change the password. To avoid typing errors, the password must be entered twice. The new password is active after you leave the dialogue box by

clicking the [OK] button. If you want to discard the changes and stay with the old password, leave the dialogue box by pressing the [Cancel] button.

8.1.1 Language

To activate German, English, French or Spanish language settings.

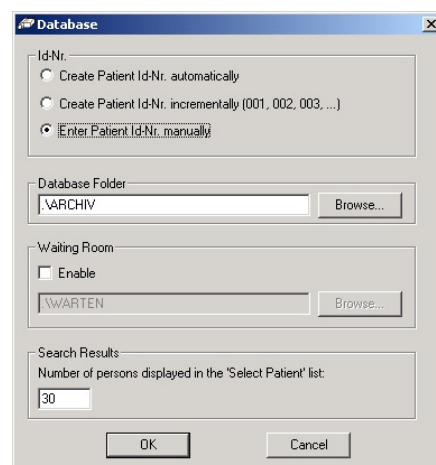


8.1.2 Database

In paragraph 'Id-No.', the format of the patients ID is determined.

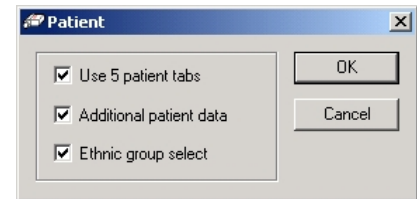
In the paragraph 'Database', the user can define the folder, where the patient-archive has to be stored.

Paragraph 'Search Results' defines the number of patients, displayed in the main window as a result of the 'Search Patient' request.



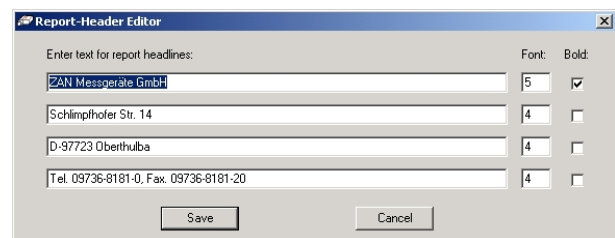
8.1.3 Patient

This turns on multiple tabs in the main window and activates entry of additional patient data and ethnic group.



8.1.4 Headlines

This dialogue box will change the headlines on the printout of the reports.

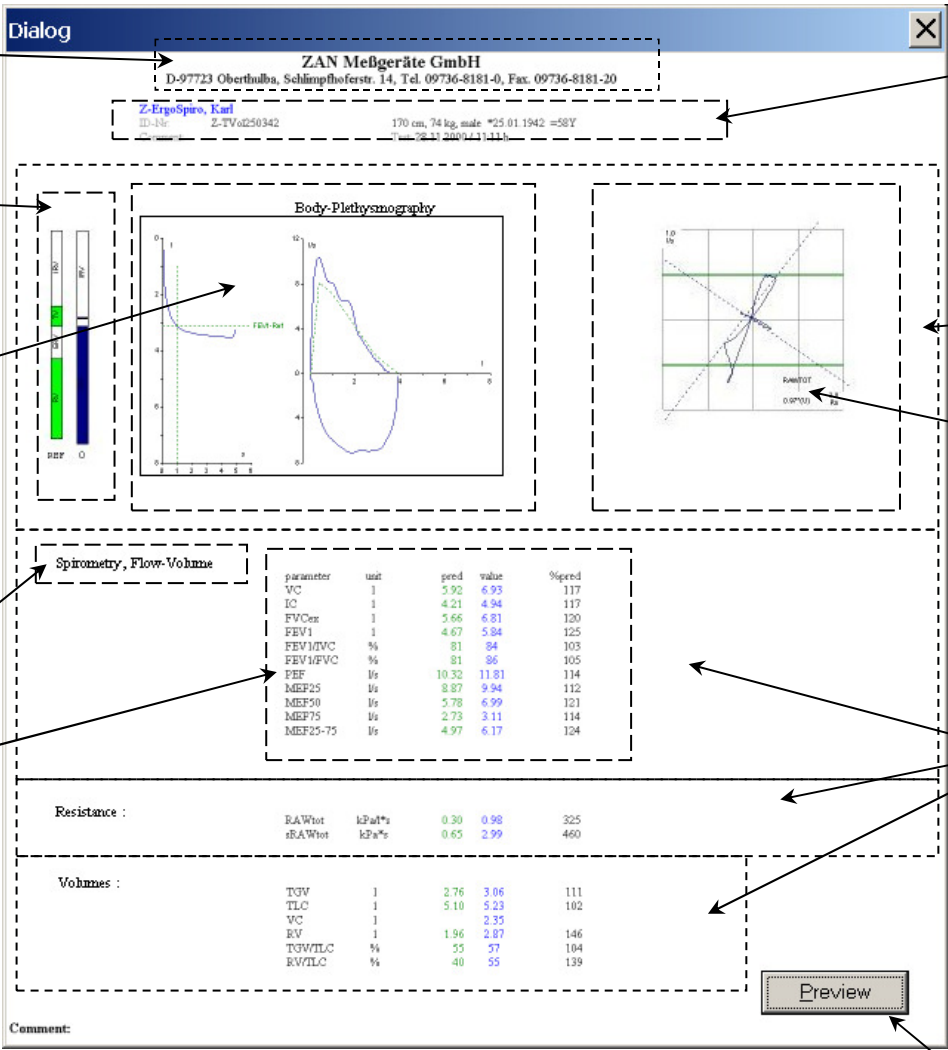


8.2 Report Designer

The ZAN GPI software provides many preconfigured printout forms, which match the most common formats. But in some situations there might be a need to adapt the existing templates to particular demands. In order to give the customer some control over the printed output of the program, nSpire Health provides a simple but sophisticated tool to revise the layout of the print templates.

8.2.1 Overview

Every report is derived from the same basic template. This template can be looked at as one side of a printer page. The page is divided into areas. Every area represents a particular element and provides specific editing features. For example: there are text areas which can be edited, other areas contain graphics in which styles can be selected from a menu.



The screenshot shows the 'Dialog' window for the ZAN Report Designer. It contains several sections and controls:

- Header (edit):** A text area at the top containing company information: 'ZAN Meßgeräte GmbH', 'D-97723 Oberthulba, Schillinghoferstr. 14, Tel. 09736-8181-0, Fax. 09736-8181-20'.
- Patient ID (automatic):** A text area containing patient information: 'Z-ErgoSpire, Karl', 'ID-Nr. Z-TV0250342', '170 cm, 74 kg, male *25.01.1942 =58Y'.
- Volumes (toggle):** A vertical bar on the left with a green 'ON' indicator and a blue 'OFF' indicator.
- Graphics (selected):** A section containing two graphs: 'Body-Plethysmography' and a smaller graph on the right.
- Table caption (edit):** A section titled 'Spirometry, Flow-Volume'.
- Table values (selected):** A table with columns: parameter, unit, pred, value, %pred.
- Tables:** A section containing two tables: 'Resistance' and 'Volumes'.
- Preview button:** A button at the bottom right labeled 'Preview'.

Annotations with arrows point to these specific areas from the left and right margins of the image.

Some areas can be switched off or on (toggled) while others are automatically filled with corresponding data etc..

To activate the editing functionality of an area move the mouse cursor over the desired region until the cursor shape changes to the 'hand' symbol and press the left mouse button. The editor recognises the area the cursor is in and opens the corresponding dialogue, editor or menu.

After modification, the result can be viewed using the 'Preview' button. This opens the MS Internet Explorer window showing the new content of this template.

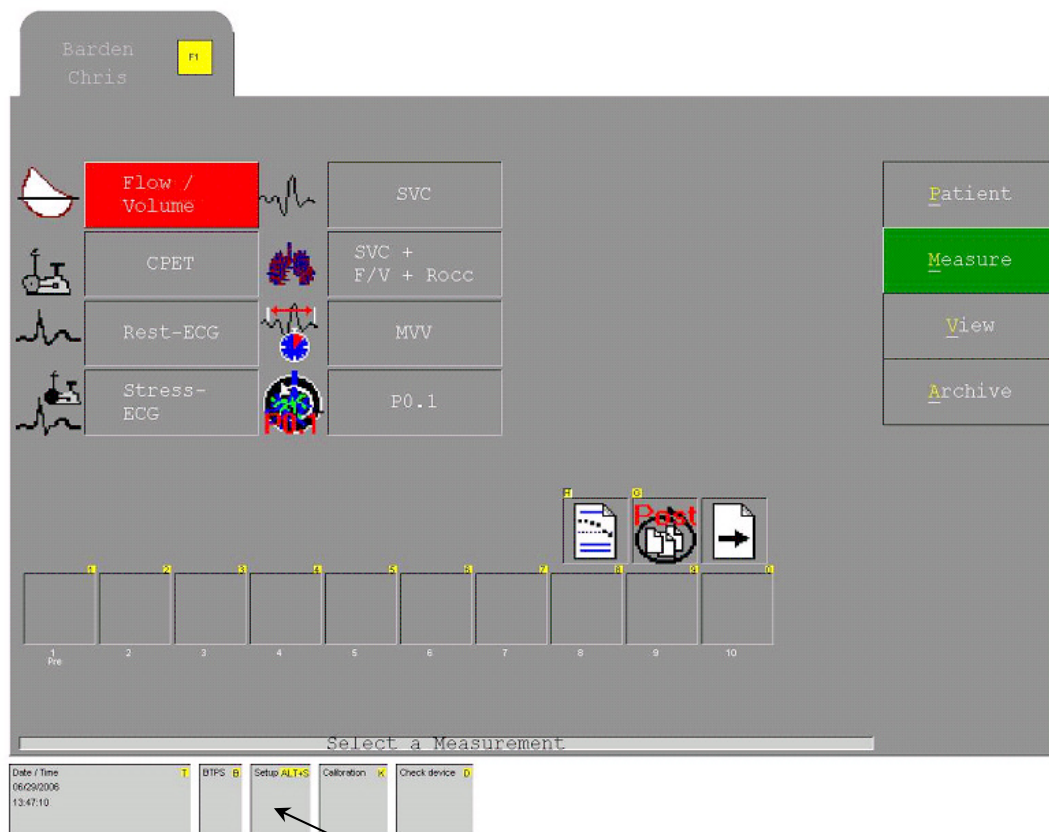
Note: The changes are not visible in the designer window. The designer window acts like a big graphical menu and is designed just to select items to be edited or modified. To see how the editing impacts the layout, you need to use the preview button.

Note: Please select the appropriate font size in you MS Internet Explorer.

To close the designer window, use the 'Close' icon  in the upper right corner. A verification dialogue will pop up to ask you if the changes should be stored permanently or not. This dialogue will only appear if changes have been made to the template.

8.2.1.1 Invoking the Report Designer,

From the main menu select Setup by either pressing ALT +S or clicking the button with the mouse.



Select the Set-up with ALT-S or a mouse click

This opens the 'Setup' window. From the menu select the drop down list 'System'. In this list you find the item 'Reports'. Move the mouse cursor over the 'Reports' entry and the 'Protocols' subitem pops up. Click on 'Protocols' to invoke the 'Report Selection' dialogue.



Setup window with open drop down menu

8.3 Report Selection Dialogue

This dialogue has two different functions:

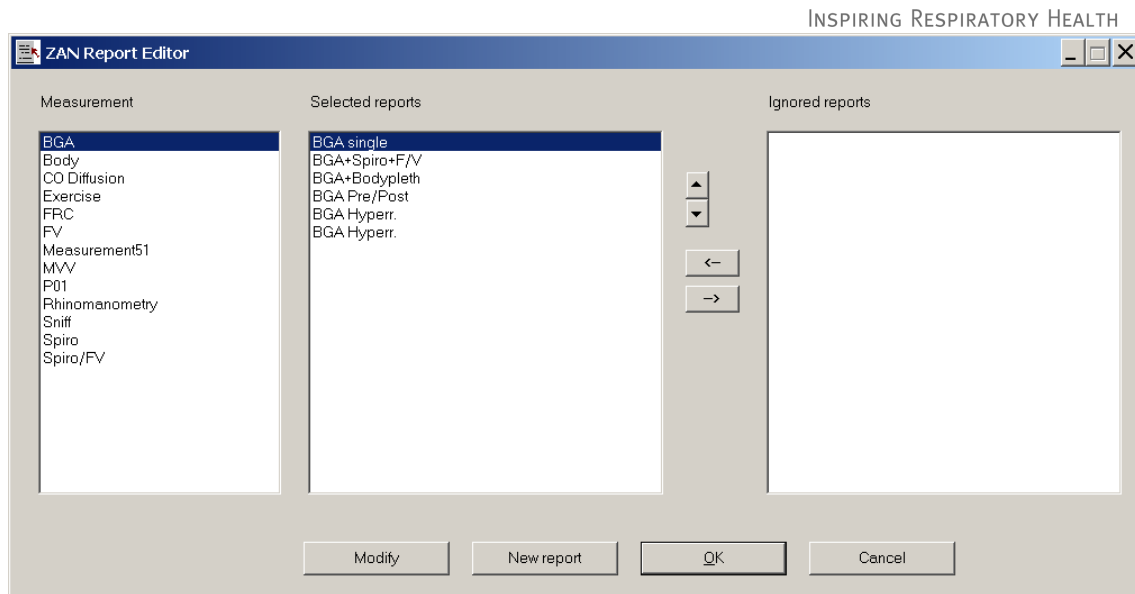
1. Select a report for editing
2. Organise the print options reports list

Three listboxes are in the dialogue window.

1. Measurement
2. Selected reports
3. Ignored reports

In the leftmost listbox, all installed measurement methods are displayed. If you select one of the measurements, the corresponding list of installed reports for this method is displayed. The list can be divided in an active part (selected reports) and a passive part (ignored reports). Only active reports are displayed in the print options and can be selected during the measurement. Use the arrow keys to move a report from the selected to the ignored list and vice versa, as well as to move a particular report to another vertical position in the selected list. In the print selection, the reports appear in exactly this order, so it is possible to move more reports used most often into top positions for easier handling.

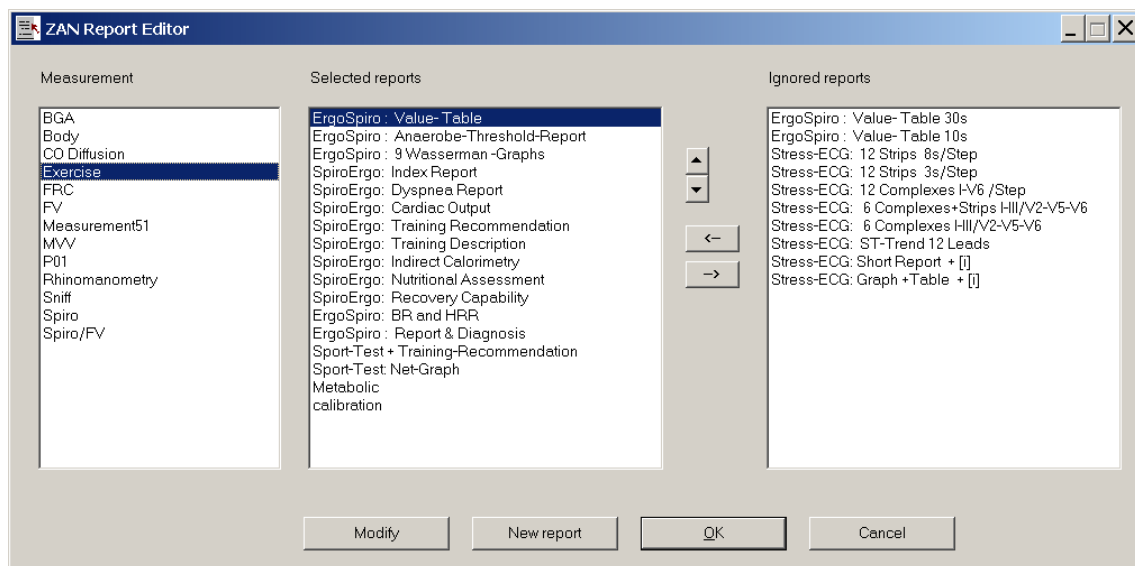
No report template will be deleted. They only remain disabled in the 'ignored' list until they are needed.



Report organiser and selection dialogue

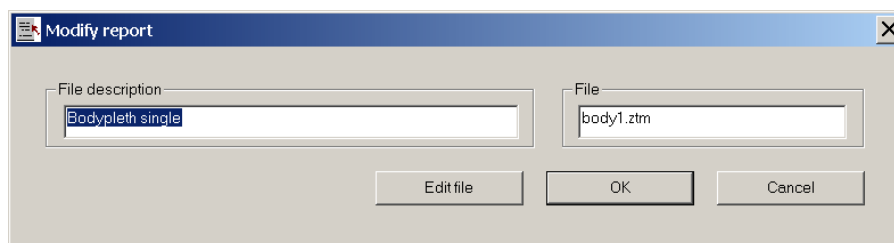
Selecting a report requires three steps:

1. Select the desired measurement method in the leftmost listbox (The list of available reports is displayed)
2. Select the desired report from the 'Selected reports' listbox.
3. Press the [Modify] button to enter the 'Report Designer'



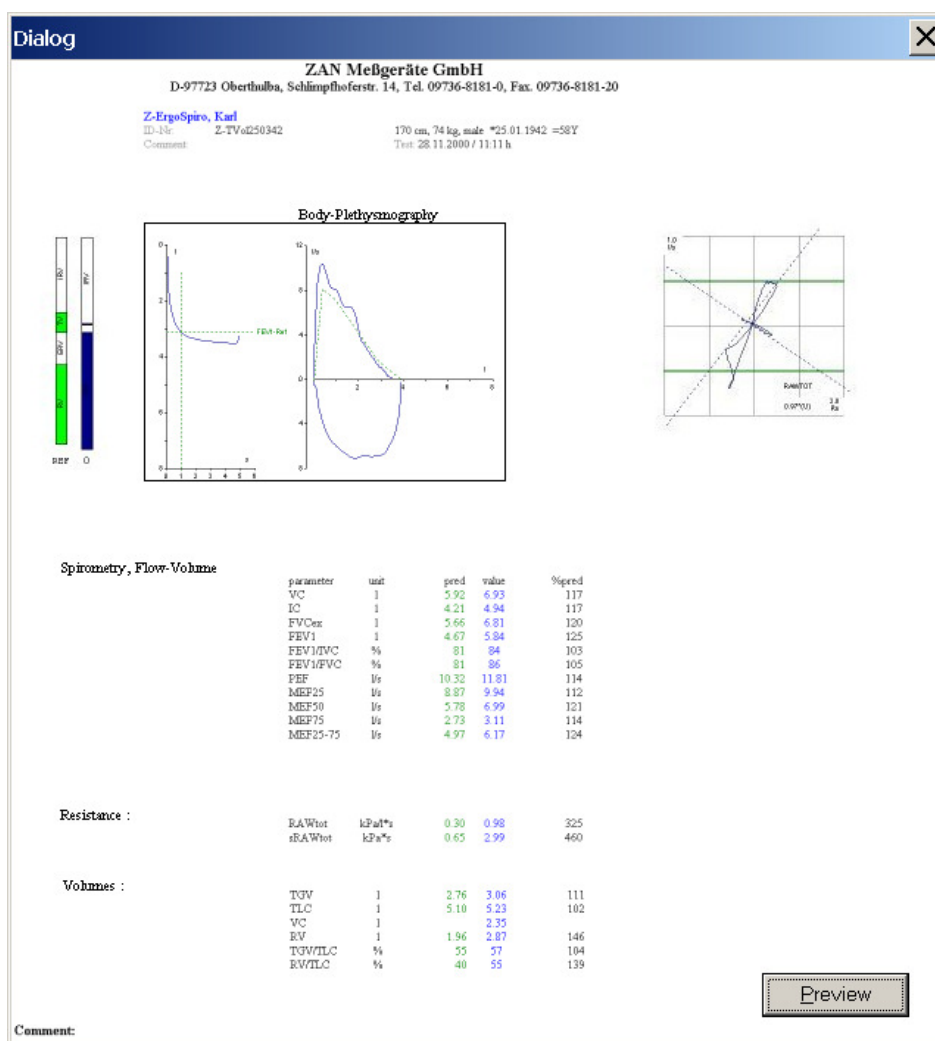
8.3.1 Editing the Report

The first option is to change the description of the report, displayed in the listbox and the print selections.



Press [OK] to save the changes made in the File Description text box or [Cancel] to abort the process.

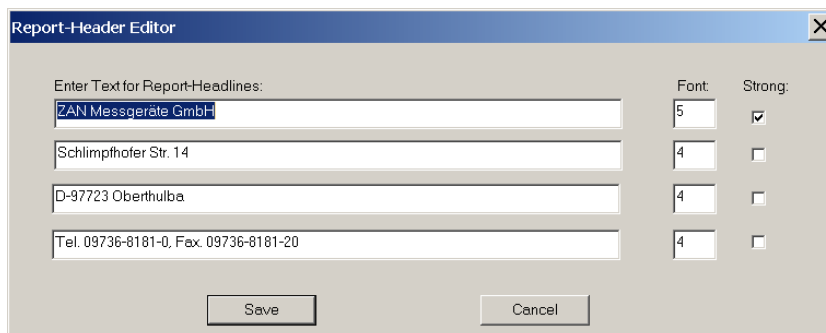
The [Edit file] button can be used to enter a basic file editor to review the internal template file. The Report Designer Window appears on the screen.



Report Layout Template

8.3.2 Modifying the Header

To edit the Header, use the mouse pointer to click into the header area. A dialogue pops up which allows you to change the particular lines in the header



Report-Header Editor

Enter Text for Report-Headlines:

ZAN Messgeräte GmbH

Schlimphofer Str. 14

D-97723 Oberthulba

Tel. 09736-8181-0, Fax. 09736-8181-20

Font: 5 Strong: ☒

4 ☐

4 ☐

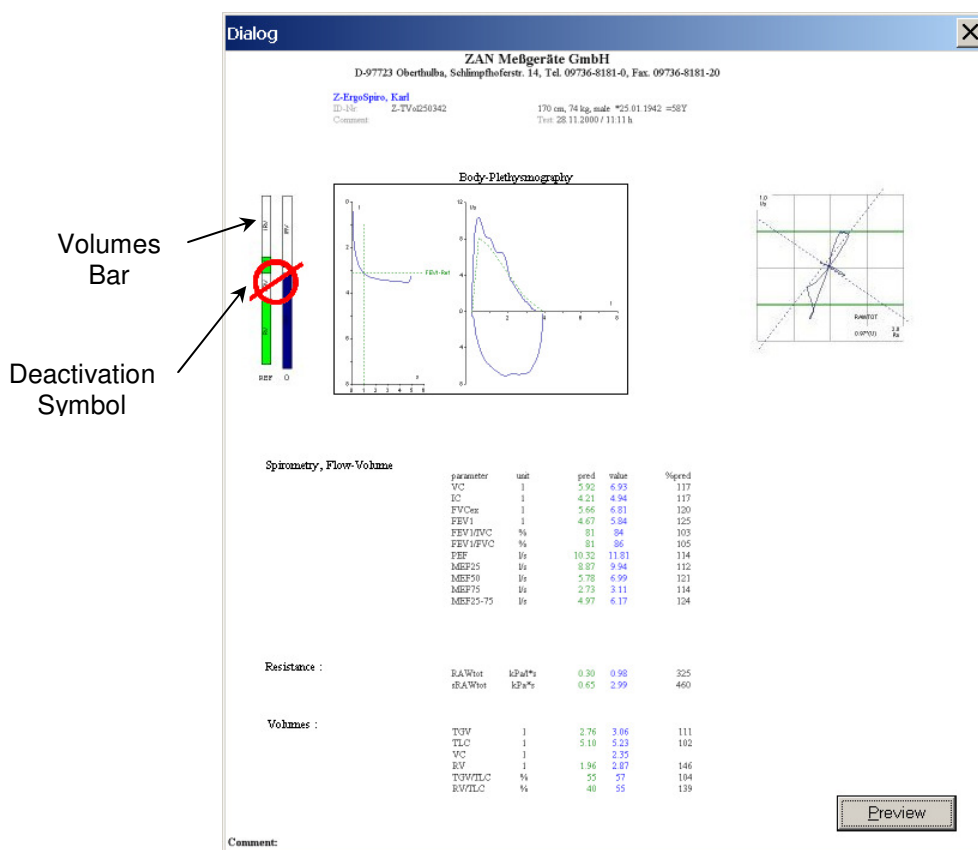
4 ☐

Save Cancel

Note: Since there is only one global header definition file in the system, this will change ALL headers on ALL printouts.

8.3.3 Switching the Volumes Bar

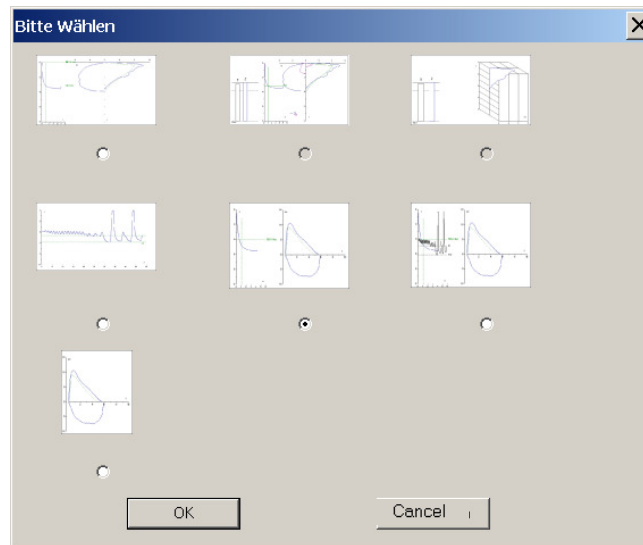
The Volumes Bar is the leftmost graphic element in the graphics area. By clicking on it, it can become activated or deactivated, which means, that it will or will not be printed on this report. If the Volumes Bar is deactivated, the red symbol is displayed over the graphic, like shown below. Otherwise the element is active.



Volumes Bar deactivated

8.3.4 Selecting a Measurements Graphic Type

Clicking on the mid part of the graphics area opens the corresponding list of available graphic types.



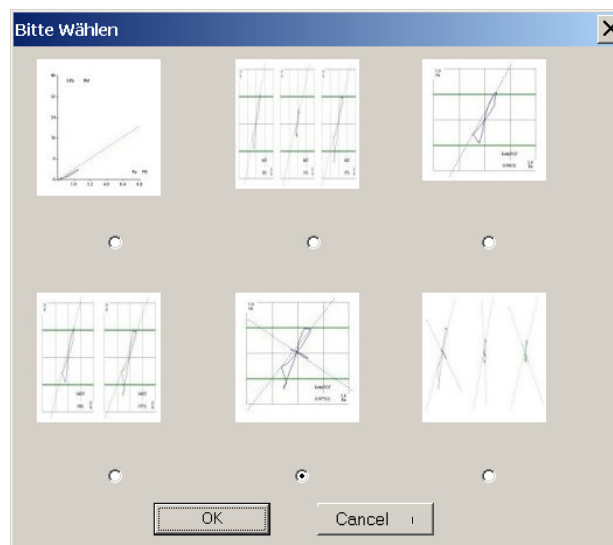
Available graphic types.

In some cases, not all possible graphic types are valid for the selected report. Those graphic types can not be selected and the corresponding radio button fields are disabled (greyed). Only one graphic type can be selected.

Press [OK] to activate the selection or [Cancel] to abandon the selection.

8.3.5 Select a Results Graphic Type

Clicking on the right graphic element opens the results graphic types selection. The behaviour is the same as in the measurement graphics.

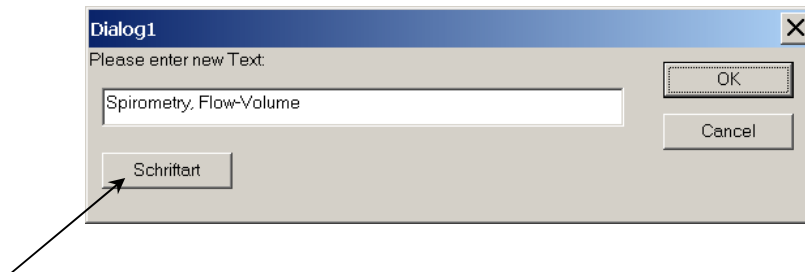


Available graphic types

8.3.6 Editing a Table

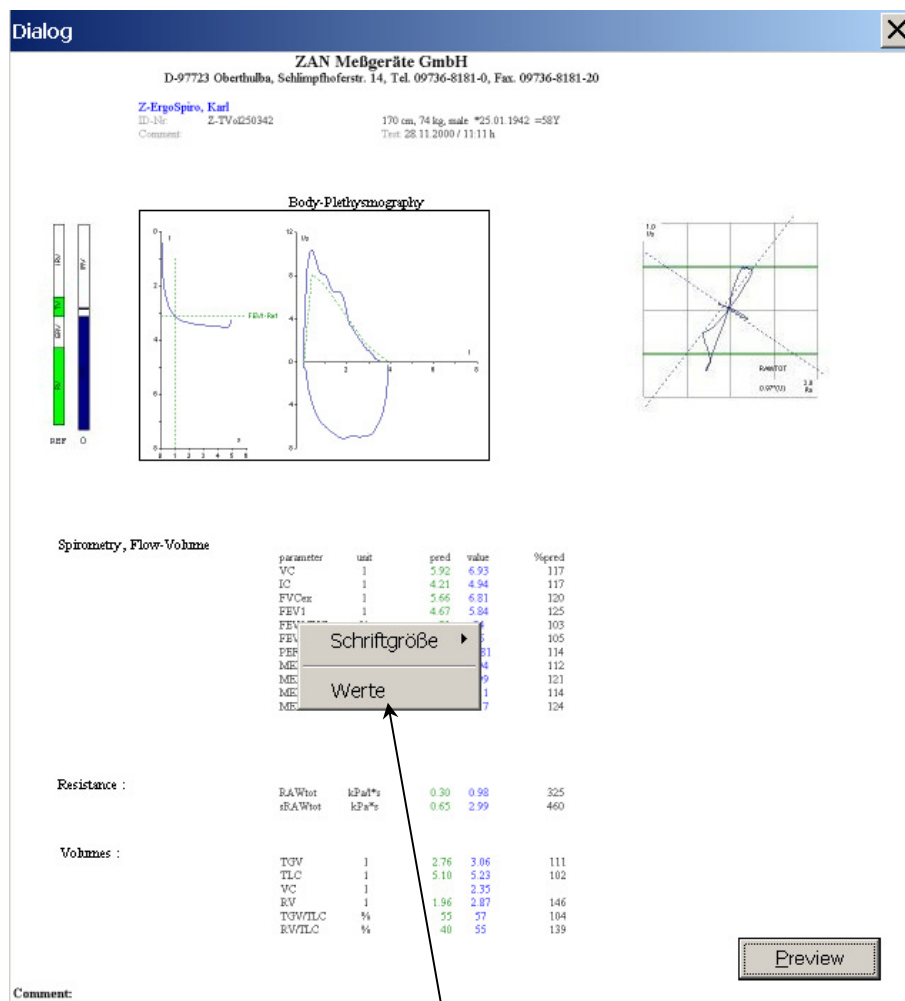
Below the graphics area, the tables area begins. A table is divided into a caption and the table itself. The caption is displayed on the left of the table body.

To edit a caption of a table, click on the requested caption and the edit dialogue pops up.



Use the [Schriftart] button to select a font.

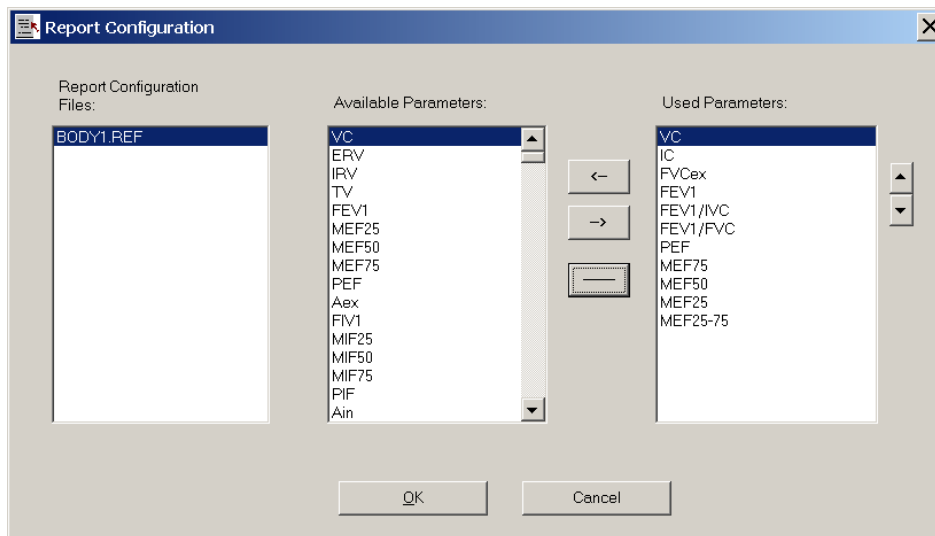
Use [OK] to activate the changes or [Cancel] to leave the content unchanged.



When you click into the table, the system offers two options in a pop up menu:

- 1 [Schriftgröße] : means font size, to select a different font size for the table contents

- 2 [Werte]: means parameters, to select a subset of parameters from a menu of available parameters, to be displayed.



Selection of values to be displayed in the table

Use the arrow keys to move a particular item from the 'Available' to the 'Used' list and vice versa. Use the arrow keys on the right most side to move an item to the desired vertical order. Pressing the



button inserts a separator at the cursor position to improve readability of the table. Like the parameters, the separator can be selected and moved vertically. To remove a separator, simply select it

with the cursor and use the left arrow button

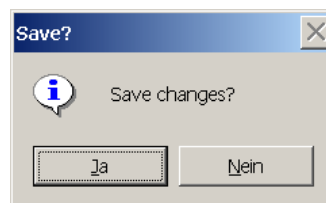


After all changes have been applied, use the [OK] button to activate the changes. Pressing the [Cancel] button will discard all changes.

The dialogue will be closed and the user returns to the overview window.

8.3.7 Saving the Changes

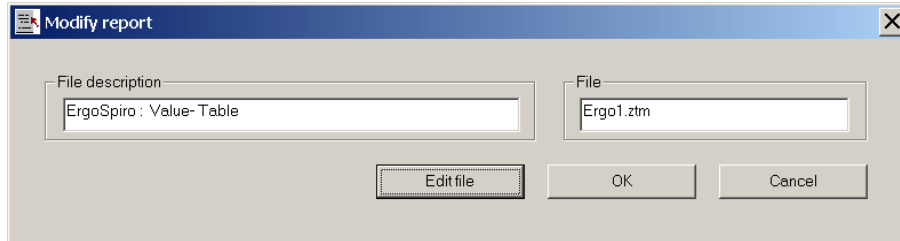
Whenever changes have been made to a template, a verification dialogue pops up, when the user attempts to close the overview window.



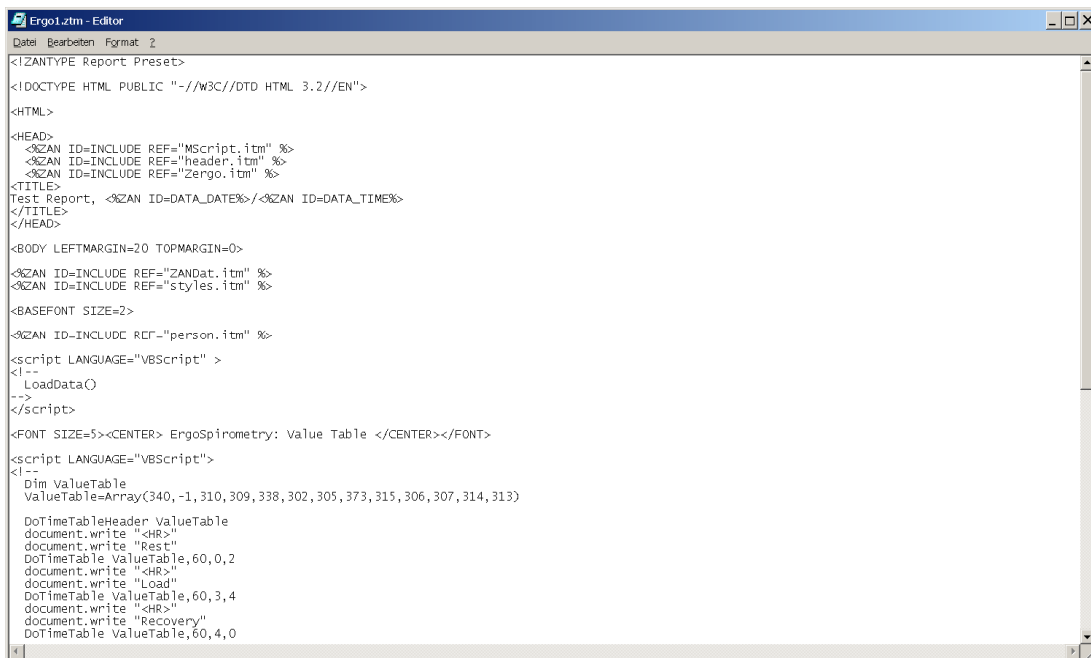
If you want to save the changes press the Yes button, else the changes will be abandoned and the old design of the report is restored again.

8.3.8 Disabled Options

If you use the edit file option, a html file is opened in the Notepad editor.



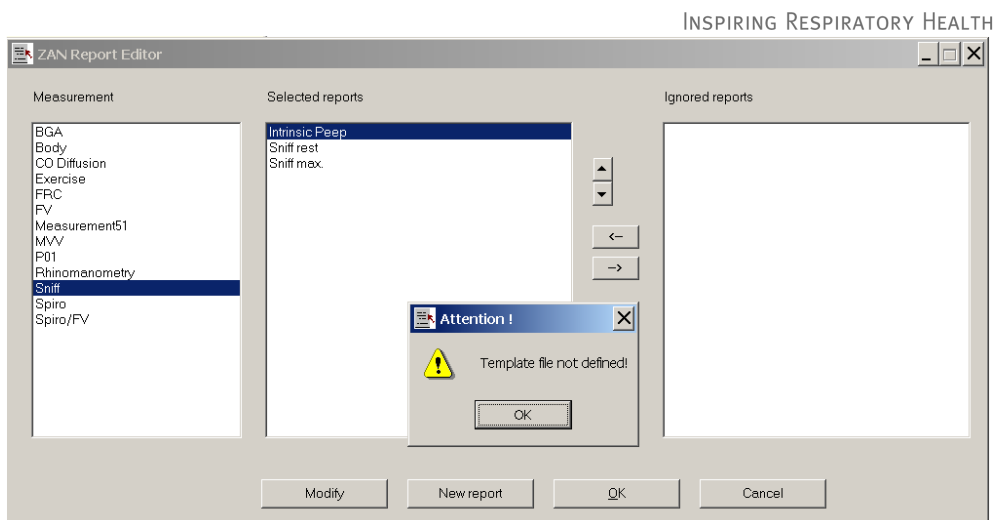
Edit file dialogue



Notepad with a raw template file open

This edit option is not intended to be used by unauthorised personnel. Please do not use this option. It will be disabled and removed in the next version.

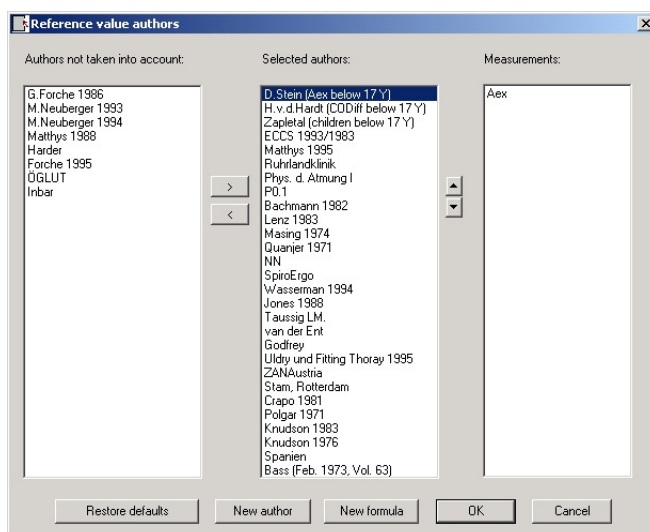
When you try to use the [New report] option, you will always get a "template file not defined" error message



This option has been disabled and will be removed in the next version. Please do not use this option.

8.4 Reference Value Editor

You can define the use of the reference value tables of different authors according to your demands.

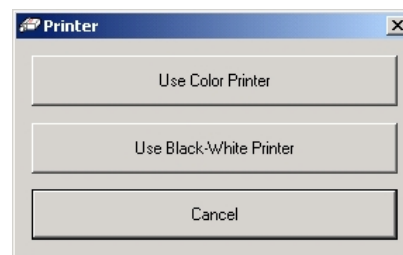


Add an author with [New Author] and a new equation with [New Formula]. You can also change the order in which the associated table is used. To activate and deactivate a particular table, use the arrow buttons on the left.

8.5 Printer Configuration

This dialogue box is used to define the printer type

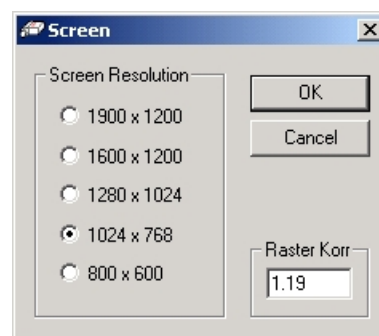
Note: ZAN always uses the Windows® default printer



8.6 Screen resolution

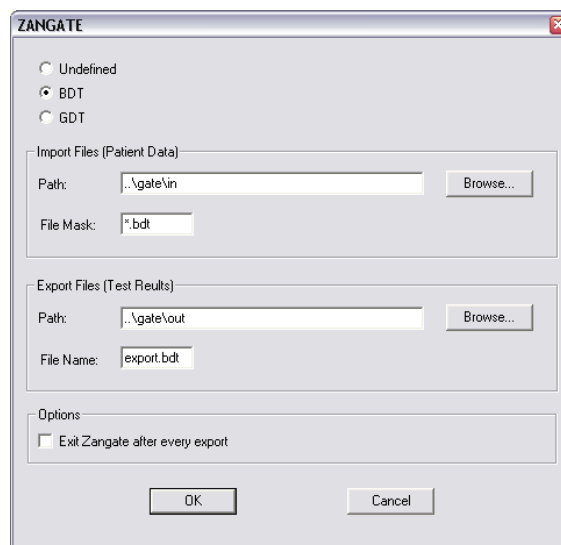
This dialogue defines the resolution of the computer monitor. Please select the appropriate setting. This setting will not change the basic Windows® setting, but is used to calculate the graphics and print outs internally.

Raster size, for ECG display for instance, is also defined in this dialog. The system detects correct values for this parameter automatically and should not be changed.



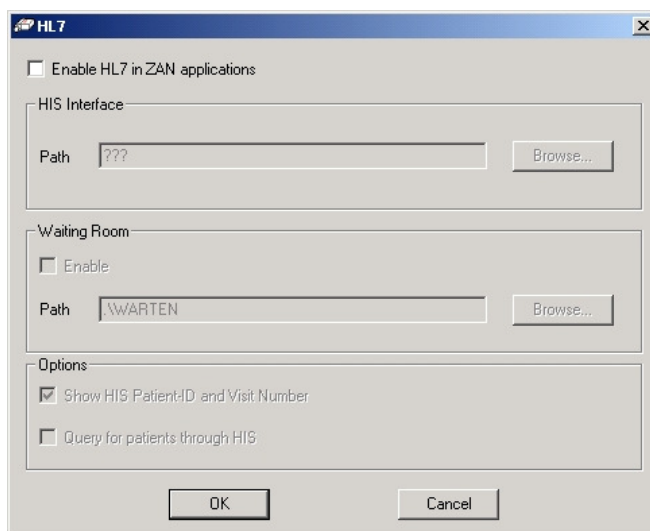
8.7 ZanGate (Optional)

When using the ZAN software in connection with a CPRS you can define basic communication parameters in this dialogue box. BDT and GDT are data formats used in Germany to perform standardised data exchange with remote systems.



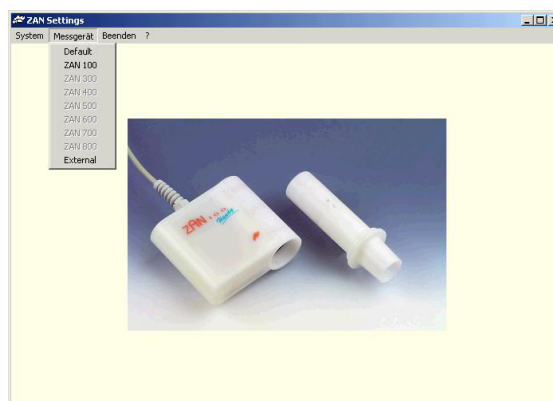
8.7.1 HL 7 (Optional)

This dialogue box is used to activate and configure HL7 communication with external hospital information systems.



8.8 Device Settings

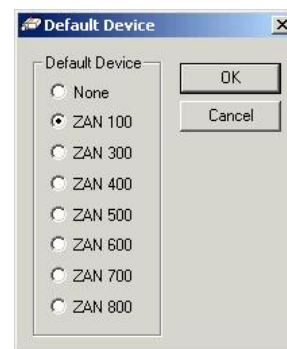
The „Device“ setting shows the following options.



8.8.1 Default Device

Select your default device using this dialogue box. The default device must always be the main device of the system.

E.g. select ZAN100 when using a ZAN100USB device

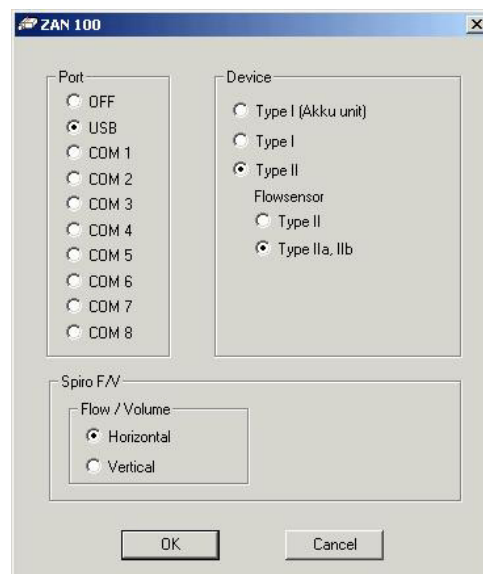


8.8.2 Device specific settings

Select the port, where your ZAN100 device is connected to. With the ZAN 100 USB it is always the USB port.

Please do not change settings in the 'Device' segment. These settings should be changed by qualified personal only. Please refer to you dealer or the ZAN service, if you need to make changes here.

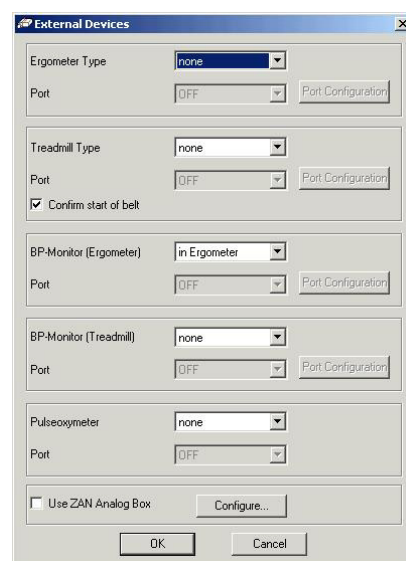
Spiro F/V toggles the display of the Flow/Volume chart between portrait and landscape.



8.8.3 External Devices

Select the type of external device. The device is activated when you change the type in the drop down box from 'none' to a different value. This will also activate the associated port dialogue box.

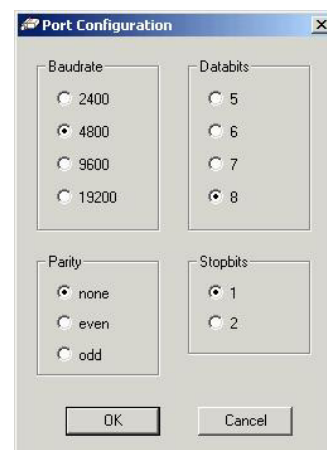
Select the port, where your external device is connected to.



After selecting the port, you can set-up the corresponding port configuration by clicking on the [port configuration] button.

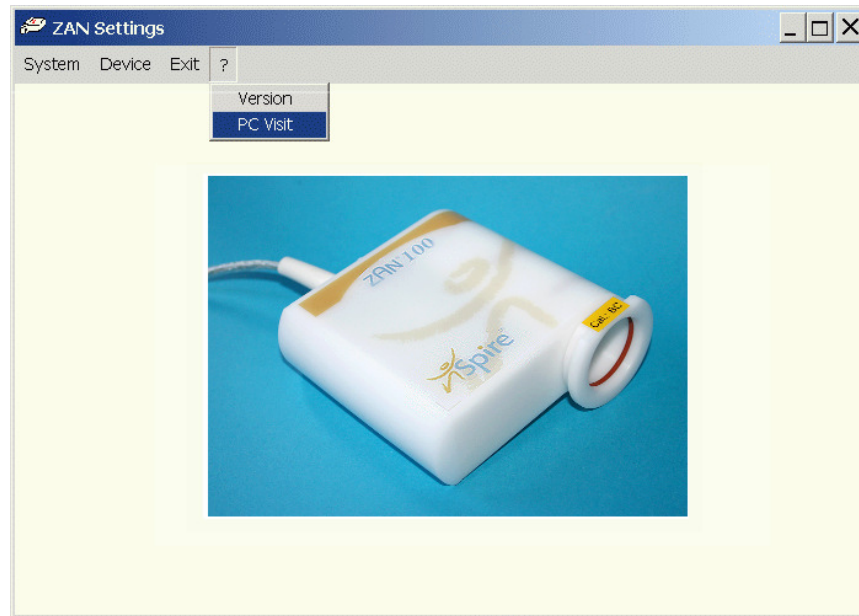
This dialogue allows you to define necessary parameters like baud-rate, data format, parity, and stop bits for a serial port for example.

Please refer to the manual of the external device to find the correct settings.



8.8.4 On line support

nSpire Health uses the remote control software "PC-Visit" for on line support. PC-Visit is not active during normal work and needs to be started on demand. To invoke PC-Visit, select the corresponding item from the "Settings" Menu like shown below.



For more information refer to the product documentaion of PC-Visit.

9 Safety, Maintenance, Service

9.1 General Security Informations

We explicitly declare that the regulations in this manual are according to the MPG and the DIN EN 60601-1.

The particular regulations are not part of this manual.

Use of devices and software is exclusively reserved for medical diagnostic and therapeutical purposes. Only trained and experienced personal should be allowed to use the devices on patients.

If there is damage to a part or system due to misuse, VDE protection is broken. In this case disconnect the device from any external power and contact your ZAN service before any further use.

nSpire Health GmbH takes responsibility for security and reliability of the device only if:

- All changes, extensions, repair or other work is done exclusively by authorised personnel of the nSpire Health GmbH.
- Electrical installations of the room in which the device is operated conforms to VDE 0107.
- Operation of the device is done according to the instructions in the manuals.
- The instructions in the technical description have been observed carefully.

Caution: Never operate medical devices of nSpire Health GmbH in an environment which is endangered by explosions.

Never extend cables or tubes without the explicit permission of nSpire Health GmbH.

In case of damage of current carrying parts or parts which have to carry weight, set the equipment out of order, disconnect all power cables and report to nSpire Health GmbH service or your local medical device technical department.

Make sure that all networking connections are equipped with indirect coupling.

Observe carefully the instructions in the "Disinfection" chapter.

The user is responsible for the correct use of disinfection and proper set-up of the equipment.

Electromagnetic Interference

Medical devices require special care concerning electromagnetic interference. All devices have to be installed and operated in accordance with the instructions and regulations provided with the equipment.

- Strong transmitters must not operate near the equipment.
- Portable HF devices (such as Mobiles for example) can possibly influence the functionality of devices. Avoid using such devices near nSpire equipment.

- The devices are tested up to a level of 3mV/m and should not be exposed to electromagnetic fields of a higher level.
- Do not operate the device near heavy current powerlines or devices.

9.2 Device specific Security Information

9.2.1 Flowhandy ZAN100 USB

The Flowhandy ZAN100 USB is part of all following devices.

Caution The Flowhandy ZAN100 USB may only be operated in connection with peripherals which fulfil the DIN EN 60950 or DIN EN 60601-1 for medical equipment and have a valid CE certification. PC devices must comply with the minimum configuration standards explained in the technical description.

Office equipment according to DIN EN 60950 is not the same as medical equipment according to DIN EN 60601, therefore a minimum distance of 1.5 m between the patient and the device which does not follow DIN EN 60601-1 is required.

E.g. The medical device Flowhandy ZAN100 USB is in accordance with DIN EN 60601-1 but the PC is only DIN EN 60950. The Minimum distance between the patient and the PC must be at least 1.5 m, while there is no need to keep distance between the Flowhandy ZAN100 USB and the patient.

If this is not possible because of reasons such as small rooms etc. we strongly recommend the use of a ZAN system desk which provides indirect coupling for the complete equipment and fulfils the necessary requirements according to the medical product law.

9.2.2 ZAN500 Body Box

Caution The ZAN500 Body Box requires the ZAN system desk for safe and legal operation.

Do not pull the door downwards while it is open. This could cause the whole chamber to fall over.

The patient must know how to open the door of the chamber from inside by his/herself.

Never leave the patient alone inside the chamber without supervision.

All connections and cables between the chamber and the system desk are purposefully short so as to avoid stumbling over them. Make sure all staff are aware of the cables to avoid any accidents.

9.2.3 CO Diffusion (ZAN300) and FRC (ZAN310 FRC Helium) Options

Caution The ZAN300 as well as the ZAN 310 FRC Helium must use the specially designed ZAN system desk for safe operation.

Extension of any tube will cause inaccurate results during measurement and is therefore, strictly forbidden.

Tubes for CO diffusion and FRC measurement must not be bent.

Avoid sudden major changes of environmental parameters such as temperature for example. This will create faulty measurement and could damage the analysers.

9.2.4 ZAN600 USB

Caution The ZAN600 USB may only be used in connection with devices which comply at least with the DIN EN 60950 Norm and have a valid CE certification.

The devices must not be operated in an environment which is endangered by explosions.

The ZAN600 USB must be operated with the original power supply or with the built in power supply of the ZAN system desk, which complies with DIN EN 60601-1.

9.3 Using customer supplied equipment

The devices built by nSpire Health GmbH and the nSpire system cart together form a unit which is fully compliant to German MPG. These sets are manufactured in a way that allows connection to a PC, which is not protected by the security system built into the nSpire system cart.

If the nSpire devices are to be connected with the PC of a different provider, consider the following instructions:

1. The PC has to meet the minimum requirements defined in the technical description of the software manual.
2. The PC has to meet the DIN EN 60950 norm and have a valid CE certification. If not, the patient could possibly get an electric shock when touching the device, because of unequalised ground potential differences between the PC frame and the ZAN device.
3. The distance between the patient and the PC during operation must be more than 1.5 m.
4. Within a distance of less than 1.5 m, no nonmedical device may be associated with a medical device.
5. Within 1.5 m distance to the patient no network connections may be installed without a 4kV proof disconnection (indirect coupling).

Caution Mains operated devices, which comply to DIN EN 60950 cannot be compared to devices complying to DIN EN 60601-1 for medical devices. For this reason, medical devices are equipped with galvanic disconnectors (indirect coupling) which disconnect the medical device from the PC System according to well defined rules. But a minimum distance of 1.5 m from the device to the patient is necessary to keep the effectiveness of the disconnectors.

If this is not possible, nSpire Health GmbH strongly recommends the use of the nSpire system cart, which is able to completely disconnect the PC from the mains.

9.4 Connecting Devices

Power cables and data connections should be fastened in a way, that they cannot disconnect accidentally. Always check if the device is built in accordance with the regulations in the corresponding law.

E.g. In Germany a maximum overall discharge defined in DIN EN 60601-1 must not be exceeded, when additional devices are connected.

9.5 Special Precautions With Treadmills

Treadmills use very powerful engines. Only treadmills designed according to the regulations for medical products should be used.

Always position the treadmill so that if the patient falls accidentally, he/she does not encounter injuries.

If the patient falls, he/she will be moved backwards. The place behind the treadmill should therefore be free from any objects/equipment. We recommend placing padding on the walls behind the treadmill.

Depending on the patients condition, a special safety belt might be necessary to prevent the patient from falling.

On any malfunction, such as a power failure, the patient must leave the treadmill immediately, because some treadmills accelerate on recovery (skipping the normal start programme) and this may cause the patient to fall off.

Also a sudden stop of the band must be avoided because it could make the patient fall onto or over the front of the treadmill.

Read the safety information by the treadmill manufacturer carefully.

9.6 Product Label



The serial-number is defined as:

The 1. number is the year. (The 4 means 2004 for example).

Numbers 2-4. define the product code (800.in this example)

Symbol Definitions



If a part or product is marked with this symbol, it is compliant to DIN EN 60601-1, Type BF.



If a part or product is marked with this symbol, it is compliant to DIN EN 60601-1, Type B.



If a part or product is marked with this symbol, it is compliant to DIN EN 60601-1 Type BF with additional defibrillator protection. This means, the device is isolated from the mains and has a built in protection against over voltage.



Caution! Read the accompanied manuals.



device of protection class II.

IPX0

Not protected against liquid.



protective conductor connector



This product is compliant to regulations for medical products 93/42/EWG and German law MPG.

The number describes the institute which performed the CE certification.

In this example it is the Eurocat GmbH institute in Darmstadt.

If necessary, nSpire Health GmbH is able to present the corresponding documents, which allow application of this symbol on the device.

9.7 Maintenance Information

9.7.1 Gas Container Valves

Caution:



Do not open the valve to the absolute ending and leave it in this position. The valve might be blocked irreversibly by the internal pressure of the container. Always take one half turn back, when the opening end has been reached.

9.7.2 Pressure Reducer

Pressure reducers need periodical maintenance. Please refer to the manufacturers manual for the correct maintenance intervals.

9.7.3 Flow Sensor

Lifetime:

The Flow Sensor is directly exposed to the patients breath, disinfective agents and a permanent change of humidity and temperature. That makes it impossible to guarantee a minimum lifetime. The typical lifetime of a Flow Sensor is about 5 years according to customer reports.

Calibration:

Calibration is recommended after every disinfection or after exchange of the Flow Sensor.

Calibration can be performed by the customer using the 1L calibration syringe. The syringe is available from nSpire Health GmbH. The necessary software is already included in the standard software package.

If the customer does not want to calibrate the Flow Sensors, they can send them to nSpire for calibration.

If the calibration results show significant deviations from the reference values, the Flow Sensor should either be replaced or re-encoded by nSpire.

Check: There are two criteria to determine if a Flow Sensor produces correct results:

1. Raw Inspection of the membranes. If the membranes are mechanically damaged, the Flow Sensor should not be used.

2. Precise Calibration.

Deviation in/ex > 6% or

deviation 1.00 <> 10%

The Calibration Software provides automatic detection of deviation and will give a warning message. Additionally, the correction coefficients cannot be saved.

9.7.4 Flowhandy ZAN 100 USB

Lifetime: The lifetime of a Flowhandy ZAN100 USB depends strongly on usage and mechanical strain. When used carefully, lifetime is only limited by the lifetime of the sensors and the electronic parts inside.

The manufacturer of the Pressure Sensor guaranteed a maximum error of less than $\pm 0.2\%$ over 1 million maximum pressure changes. Under normal conditions the maximum range will never be reached. A typical flow measurement produces about 20 changes in pressure. If a physician uses this device frequently, and about 50 patients per day are tested, this would approximately define a minimum lifetime of 5 years for the Pressure Sensor.

Calibration: Calibrating the Flow Sensor simultaneously performs a calibration of the Flowhandy.

Maintenance: **nSpire recommends a technical check-up after ca. 1000 measurements or after 12 months of use (which ever happens first).**

The service is done at nSpire Health GmbH and includes tests of the following parameters:

- Tightness
- Mechanical condition
- Measurement precision
- Data communication
- Linearity

The customer will receive a written test report with all results of the service from nSpire Health GmbH.

The customer can also check mechanical conditions as well as calibrate the system with the 1L Calibration Syringe, which is available from nSpire Health GmbH.

9.7.5 ZAN500 Body Box

Lifetime: The lifetime of the ZAN500 Body Box depends on how the device is used and how much mechanical strain the device has had to endure. When used carefully, lifetime is only limited by the lifetime of the sensors and the electronic parts inside.

Under normal conditions a lifetime of 8 years or more is usual.

Calibration: Calibration of the bodyplethysmograph includes volume calibration. The latest detected calibration factors are saved and used by the software

We recommend calibrating the bodyplethysmograph once per day.

Please refer to the corresponding manual, chapter 'Calibration' for details.

Caution: nSpire Health GmbH recommends a service of the system by nSpire Service Dept, once a year.

The customer will receive a written test report with all results of the service and the calibration values from nSpire Health GmbH.

9.7.6 CO-Diffusion Option (ZAN300)

Lifetime: The lifetime of the CO-Diffusion option is limited by the CO/CH₄ analyser. Depending on how often it is switched on and off, it lasts between 3 to 6 years.

Another wearing part is the suction pump. The manufacturer guarantees a minimum of 3000 working hours. Since the pump is only working while the CO diffusion measurement is running (which last about 1 minute,) the pump will last approx. 120 000 measurements

Calibration: A calibration of the CO-diffusion option is not necessary if the device is sent in to nSpire maintenance for a service at regular intervals.

Warning: nSpire Health GmbH strongly recommends a service of the CO-diffusion option by nSpire once a year.

The customer will receive a written test report with all results of the service and the calibration values from nSpire Health GmbH.

9.7.7 FRC Helium Option (ZAN310)

Lifetime: The lifetime of the FRC Helium option is limited by the lifetime of the He-analyser. Depending on how often the analyser is switched on and off, a lifetime between 3-6 years is usual.

Another wearing part is the suction pump. The manufacturer guarantees a minimum 3000 working hours.
Since the pump is only working when the measurement is running (which lasts about 1 minute) the pump will last about 120 000 measurements.

Calibration: Calibration is not necessary. Regular maintenance ensures proper functioning of the option.

Leak Tests: Leak free equipment is fundamental to obtain valid results.
The procedure of the leak test is described in the corresponding manual. The test should be performed at least once per week and it must be performed when the absorber granules have been changed.

Absorber: The absorber granules remove the carbon dioxide from the exhaled air. The capacity is limited and it needs regular replacement. nSpire recommends replacing the granules every 90 minutes of breathing.
Please refer to the option manual for more details.

Maintenance: nSpire Health GmbH strongly recommends a Service of the ZAN310 FRC Helium option by nSpire **once per year**.

The customer will receive a written test report with all results of the service from nSpire Health GmbH.

9.7.8 Ergo Flow Sensor

Lifetime: The Flow Sensor is directly exposed to the patients breath, disinfective agents and a permanent change of humidity and temperature. That makes it impossible to guarantee a minimum lifetime. The typical lifetime of a flowsensor is about 5 years according to customer reports.

Calibration: Calibration is recommended after every disinfection or after exchange of the Flow Sensor.

Calibration can be performed by the customer using the 1L calibration syringe. The syringe is available from nSpire Health GmbH. The necessary software is already included in the standard software package.

If the customer does not want to calibrate Flow Sensors, they can send them to nSpire for calibration.

If the calibration results in unacceptable deviations from the reference values, the Flow Sensor should either be replaced or re-encoded by nSpire.

Check: There are two criteria to determine if a Flow Sensor produces correct results:

1. Raw inspection of the membranes. If membranes are mechanically damaged, the Sensor is unusable
2. Precise Calibration:
Deviation in/ex > 6% or
deviation 1.00 <> 10%

The Calibration Software provides automatic detection of deviation and gives a warning message. Additionally correction coefficients cannot be saved.

9.7.9 ZAN600 USB

Lifetime: The lifetime of the ZAN600 USB system depends strongly on usage, strain and maintenance.

One of the main factors is the lifetime of the analysers.

A lifetime of at least 5 years can be expected under normal conditions and if properly used.

Caution: The ZAN600 USB is a medical measurement device, built according to strict legal regulations of the German MPG. Chapter 5 of the regulations demands regular supervision of the measurement precision.

nSpire Health GmbH recommends supervision by either nSpire Health GmbH or another authorised institution once a year.

In addition the user is also advised to follow the regulations concerning correct usage and proper handling.

Maintenance: A service at nSpire Health GmbH includes tests of the following parameters:

- Leaks
- Mechanical condition
- Measurement precision
- Data communication
- Linearity

The customer will receive a written test report with all results of the service from nSpire Health GmbH.

The customer is also able to check mechanical conditions and connectivities, as well as calibrate the system with the Calibration Syringe using special testgas, which is available from nSpire Health GmbH.

9.8 Service Contracts

nSpire Health GmbH offers Service Contracts, individually customised to meet the particular needs of our customers. This assists our customers correct maintenance of their nSpire products which in turn provides optimum use and reliable results.

Please contact our Sales Representatives or nSpire Health GmbH directly for more information.

9.9 Customer Service

nSpire Health GmbH co-operates very closely with our associated dealers. Together we endeavour to provide an optimum service for our customers.

Usually your dealer has good knowledge of your particular needs concerning hard and software of your nSpire products. This makes them the best point of contact to ask for assistance. They will be able to give competent answers and quick support.

Our Service Department can also be contacted directly
at :

nSpire Health GmbH
Schlimpfhofer Str. 14
D-97723 Oberthulba

Phones:

Central:	+49 (0) 9736 / 81 81-0
Customer Service	+49 (0) 9736 / 81 81-17 or -27
Sales - Germany	+49 (0) 9736 / 81 81-30
Sales - International	+49 (0) 9736 / 81 81-14
Fax	+49 (0) 9736 / 81 81-20

9.10 Warranty

The warranty covers defective materials and manufacturing for one year. Within this time nSpire will replace or repair defective parts or products at no charge (except shipping costs).

Exclusions

The warranty does not cover damages caused by the following reasons:

- Negligent handling
- Improper maintenance
- Third party software or hardware connections
- Unauthorised changes or abuse
- Neglecting storage regulations
- Operation outside of the allowed environmental conditions
- Incorrect voltage
- Mechanical damage of the Flow Sensor
- Use of unpermitted disinfection agents
- Hardware damage caused by software

The warranty starts on the day of delivery to the customer.

Terms Of Warranty

The given Warranty is exclusive. There will be no other warranty or extensions to this warranty, neither written nor verbally given. Every other warranty concerning common quality or aptitude is also limited to a one year period.

Some states do not allow the limitation or exclusion or liability for incidental or consequential damages, so the above limitation or exclusion may not apply to you.

Maintenance within the warranty period

The devices must be shipped in original packaging to avoid damage during transportation. The customer is responsible for damages caused during shipping due to improper packaging.

10 Waste Management, Recycling

10.1 Electronic Components



Some products contain electronic components. To avoid environmental risks or hazard, waste management of these components underlies particular regulations depending on local laws. These regulations may vary widely from state to state

10.2 Mechanical Components

Inside the mechanical units and accessories of nSpire devices are, as far as possible, only materials used, which can be recycled.

Most used materials are coated aluminium and POM (Polyoxymethylen, Ultraform H2320 from BASF). Refer to the waste management regulations of your state or county concerning these products. There is no need to send these products back to nSpire, they can be disposed of by the customer.

nSpire Health GmbH avoids single use components where ever possible. Only parts which can be separated and disinfected easily when contaminated, are used.

In principal only unbleached paper and cardboard is used for packing.

Packing material can be disposed of like ordinary waste.

10.3 CO₂ Absorbing substances

The absorber granules (absorbence) must be handled according to the local regulations. If in doubt, ask the waste management department of your county administration for correct information.